UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO WAVE 1**	**Master File No. 2:12-MD-02327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

RULE 26 EXPERT REPORT OF DANIEL ELLIOTT, M.D.

I. Background and Qualifications

I am an Associate Professor of Urology at Mayo Graduate School of Medicine in Rochester, Minnesota. I received an M.D. in 1993 from Loma Linda University School of Medicine in Loma Linda, California. Following graduation from medical school, I completed my surgical residency in Urology at the Mayo Graduate School of Medicine at the Mayo Clinic in 1999. I completed a one-year advanced surgical fellowship at Baylor College of Medicine in Houston, Texas, in Neurourology, Urodynamics, and Voiding Dysfunction. I then re-joined the faculty at the Mayo Clinic, where I have spent the last 15 years specializing in treatment for pelvic organ prolapse and urinary incontinence in women, as well as urinary incontinence in men. I have published over 60 peer-reviewed articles and given more than 100 hundred lectures, many of which relate to urinary incontinence and pelvic organ prolapse. A Mayo Clinic colleague and I were the first to perform robotic sacrocolpopexy surgery for the treatment of high-grade prolapse and the first to publish extensively on the subject. I have also published multiple scientific manuscripts concerning polypropylene meshes in the animal model. I am a frequent invited lecturer at medical and surgical conferences addressing pelvic organ prolapse

and stress urinary incontinence and their evaluation, treatments, surgical options, and management of complications. I recently passed the subspecialty credentialing process for Female Pelvic Medicine and Reconstructive Surgery, established by the combined boards of the American Board of Urology and the American Board of Obstetrics and Gynecology. Attached as Exhibit "A" to this report is a copy of my current curriculum vitae, which includes an up-to-date list of my publications, presentations, awards, and other academic activities, as well as my fee schedule. My recent trial testimony is listed in Exhibit "B."

II. Bases of Opinions

I have been asked to provide opinions regarding the subject of female stress urinary incontinence, its evaluation, treatments, surgical options and management of complications as well as to address the actions of Ethicon, Inc., Ethicon Women's Health and Urology, a Division of Ethicon, Inc., Gynecare and Johnson & Johnson (collectively referred to as Ethicon). The focus of my investigation for this report is on the TVT-Secur System ("TVT-S") and, specifically, the characteristics of the product that make it defective or, in other words, that make the risks to the patient outweigh the benefits to the patients. My opinions are based on my personal knowledge, experience, and my investigation in this case. All of my opinions, and the bases of those opinions, are true and correct to the best of my knowledge and belief, including those related to scientific and medical issues, which I believe to be true and correct to a reasonable degree of scientific and medical certainty. I do, however, reserve the right to supplement this report and my opinions in light of any additional material or information provided to me, including any reports submitted and/or any other discovery that is taken in this case. Furthermore, if called to testify, I would plan to use various demonstrative exhibits,

animations, video recordings, and/or anatomic models to show the relevant anatomy and surgical procedures and to describe my opinions as set forth in this report.

My opinions and conclusions regarding the TVT-S, its surgical procedure, its impact on patients and surgical colleagues, as covered throughout this report, have not been derived in isolation or from solitary data and opinion; rather, my report has been formed and influenced by multiple sources, briefly summarized as follows: my independent clinical and laboratory mesh-specific research, including clinical manuscripts pertaining to female stress urinary incontinence ("SUI"), female pelvic organ prolapse ("POP"), including mesh-specific complications; animal laboratory studies regarding the effects of polypropylene mesh and host foreign body response and inflammatory response; advanced surgical fellowship training in Voiding Dysfunction and Neurourology, which is above and beyond the normal six-year urologic surgical training; my personal surgical, clinical, and research experience implanting Prolene mesh slings; my personal surgical, clinical, and research experience as a Female Pelvic Medicine and Reconstructive surgical specialist at a high-volume tertiary center managing highly complicated SUI patients and mesh-related complications, including medical and surgical revisions and removal and treatment of synthetic mesh slings, including complications caused by the TVT-S device; my attendance and participation at national and international Urological and Gynecological surgical meetings, including but not limited to the International Pelvic Pain Society, International Continence Society, Society of Female Urology and Urodynamics, American Urologic Association, Canadian Urological Association, Mayo Clinic Urology Review, UCLA State of the Art Urology, European Urological Association Subsection of Female Urology and Subsection of Reconstructive Urology. I have prepared and given lectures at national and international meeting specifically focused on the complexities of treating female SUI and the management of

complications associated with such treatments, including but not limited to the International Continence Society meeting, Society of Female Urology and Urodynamics meeting, American Urologic Association meeting, Canadian Urological Association meeting, UCLA State of the Art Urology meeting, and European Urological Association Subsection of Female Urology and Reconstructive Urology meeting. I have had personal interactions and discussions with national and international urologic, gynecologic, urogynecologic, and general surgery colleagues regarding the management of SUI in women, manifestation of mesh-specific complications, and the treatment of mesh-specific complications. As part of my interest in being as educated and as up-to-date and accurate as possible, I have reviewed the readily available medical literature pertaining to the treatment of SUI and the management of its complications from sources including but not limited to medical journals, the United States National Library of Medicine, and the National Institute of Health.

I am a surgical journal editor and/or reviewer for 14 urologic and/or gynecologic journals (please see Curriculum Vitae for complete listing of journals) and was named Best Reviewer in Female Urology/Incontinence/Neurourology for two consecutive years (2012-2013) for the Journal of Urology. This is the highest honor awarded by the Editor of the Journal of Urology for excellence in manuscript review and preparation.

I have also performed a systematic review of internal Ethicon documents as they pertain to surgical mesh, TVT-S, the TVT-S procedure, expected SUI surgical results, expected SUI complications and rates of SUI complications, and marketing strategies designed for my surgical colleagues in urology, gynecology and urogynecology, as well as for potential SUI patients. I have also reviewed the testimony of Ethicon employees. All materials I reviewed or relied on in

support of my findings and opinions are included throughout this report and/or listed in Exhibit "C."

III. Summary of Opinions

A. Background on SUI and Treatments

1. Stress Urinary Incontinence
2. Alternative/Traditional SUI Treatment Options
   a. *Non-surgical*
   b. *Surgical*

B. The Polypropylene Mesh in the TVT-S Should Not Be Used in the Pelvic Floor Due to Known Complications and Hazards

1. Polypropylene mesh in the TVT-S is not inert and degrades
2. The MSDS for the Prolene mesh states not to use with strong oxiders like peroxides, which can be abundantly found in the vagina
3. The TVT-S mesh is heavy with small pores, causing increased tissue response, chronic inflammatory response, contraction and shrinkage of the mesh, fibrotic bridging and scar plate formation
4. Ethicon's Prolene mesh tested positive for cytotoxicity

C. The TVT-S Should Not Be Used in the Pelvic Floor Due to its Defective Design

1. The TVT-S mesh is laser cut, resulting in a stiffer product and higher incidence of complications
2. The TVT-S design is flawed because there is no way to properly tension the device
3. The TVT-S is defectively designed in its insertion instruments and technique
4. Ethicon had several preferred alternatives to the TVT-S available

D. Ethicon Failed to Disclose and/or Downplayed Adverse Risks, Complications, and Product Information in its Instructions for Use ("IFU") and Patient Brochures

E. Ethicon Failed to Provide Adequate Training for Surgeons Using the TVT-S

IV. Expert Opinions

A. Background on SUI and Treatments

1. Stress Urinary Incontinence

Female stress urinary incontinence ("SUI") is a relatively common condition in which a woman leaks urine when her body experiences an increase in abdominal pressure, which in turn increases the pressure on the bladder. The abdominal pressure (A.K.A. "stress") is caused by a wide variety of activities including coughing, laughing, sneezing, jumping, bending over, picking something up, running, or any other sudden movement that increases pressure on the bladder.

In a woman, the urine leakage often results from weakening of the muscles that surround the urethra and/or a lack of fascial support for the urethra. The fascia below the urethra serves as a sort of net to prevent the urethra from falling. SUI is much more common in women than in men, largely because of pregnancy, childbirth, menopause and hysterectomies, among other factors. Each of these conditions cause physical changes in the fascia used to support the urethra, which in turn results or contributes to SUI. There are multiple fascias, or tissues, that support the urethra, including fascia located in the area of the pelvic floor and endopelvic fascia. In a woman with SUI, these fascia fail to provide sufficient support for the urethra, allowing the urethra to move downward when there is a sudden increase in pressure, such as that caused by a cough or a sneeze. When this happens, urine leaks out of the urethra. Some SUI can also be linked to intrinsic sphincter deficiency ("ISD"), a condition in which the urinary sphincter is weakened.

SUI can have very serious effects on a woman's physical and mental health. It is not uncommon for women with SUI to stop participating in activities they once enjoyed, such as sports and other recreational activities, or to experience mental illness such as depression.

2. Alternative/Traditional SUI Treatment Options

a. Non-surgical

SUI presents in 15% to 35% of women.[1] Although some surgical treatments are typically safe and highly effective, many patients wish to avoid surgery for a variety of reasons. Regardless of the patient's willingness to commit to surgery, in most cases, it is recommended that non-surgical options be implemented first.[2]

Behavior modification & Pelvic Floor Therapy & Exercises

Simple lifestyle or behavioral modifications such as weight loss and/or avoidance of dietary irritants like caffeine and nicotine are often the first line of treatment. In many cases those options may be the only treatment necessary. Additionally, pelvic floor muscle exercises (Kegel exercises) are used to strengthen the muscles surrounding the urethra so that urine is less likely to leak. These therapies require time, effort, and commitment, but they do not have side effects and are often very effective.

Alternatively, pelvic floor electrical stimulation combined with biofeedback may prove useful. Pelvic floor electrical stimulation utilizes electrical current to strengthen the pelvic floor and improve its function. Biofeedback is a treatment regimen performed under the care of a specialist and/or physical therapist. It is a safe and effective method of increasing pelvic floor strength and has a role in helping women with mild stress incontinence. Biofeedback attempts to retrain patients on how to more appropriately use their pelvic floor muscles, thereby improving

[1] Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, van Kerrebroeck P, Victor A, Wein A, Standardisation Sub-committee of the International Continence Society Neurourol Urodyn. 2002; 21(2):167-78. Milsom I, Altman D, Lapitan MC, Nelson R, Sillen U, Thom D. Epidemiology of urinary (UI) and Faecal (FI) Incontinence and Pelvic Organ Prolapse. In: Abrams P, Cardozo L, Khoury S, Wein A, editors. Incontinence; 4th International Consultation on Incontinence; Paris: Health Publication Ltd; 2009. pp. 35–111.

[2] Hay-Smith J, Berghmans B, Burgio K, et al. Adult Conservative Management. In: Abrams P, Cardozo L, Khoury S, Wein A, editors. Incontinence; 4th International Consultation on Incontinence; Paris: Health Publication Ltd; 2009. pp. 1025–1120.

their urine control. Consequently, the patient becomes more aware of her pelvic muscles and is better able to identify and use them.

Medication

There are several medications that have been studied for the potential treatment of SUI (Topical Estrogen, α-Adrenergic Agonists, Imipramine, Duloxetine, β-Adrenergic Antagonists, and β-Adrenergic Agonists). However, to date their benefit is minimal for SUI and is essentially limited to possibly benefiting overactive bladder.

Pessaries

Pessaries have been used for thousands of years to treat POP and SUI and, prior to the advent of successful surgical options, pessaries were essentially the only viable treatment for POP and SUI. Specifically, "continence pessaries" represent an alternative or complementary non-surgical approach to the treatment of SUI. These devices work by providing a platform against which the urethra can compress during strenuous activity such as lifting or coughing. There are several studies describing the effectiveness of pessaries for treatment of SUI, but most of these studies are based on small samples of participants with short-term follow-up, which make the results questionable. Ultimately, however, due to inherent limitations of effectiveness complications such as vaginal pain, discharge, and odor, and the necessity of routine medical care, most patients with SUI discontinue using the pessary at some point.

b. Surgical

Surgeons have spent hundreds of years trying to develop successful treatments for SUI. Over time, several successful surgical techniques have been devised, but all of the treatments have the common component of reestablishing support for the urethra that has been weakened and damaged by childbirth, hysterectomy, obesity, and/or age.

Marshall-Marchetti-Krantz & Burch Colposuspension

In the 1940's, the Marshall-Marchetti-Krantz ("MMK") procedure was developed. The MMK procedure is a surgery in which the surgeon secures the neck of the bladder—i.e., where the bladder meets the urethra—to the pubic bone with a series of sutures. The Burch colposuspension procedure was developed shortly after the MMK procedure. The Burch procedure is successful in treating urinary incontinence with success rates equivalent to mid-uretheral synthetic slings. Although the Burch procedure takes longer than a procedure to implant a synthetic mid-uretheral sling, the long-term complications with Burch, particularly relating to chronic pain and dyspareunia, are minimal when compared to the complications arising from mid-uretheral synthetic slings.

Pubovaginal Slings (Autologous/Cadaveric)

In the 1980's, a major advancement occurred with the introduction of a procedure known as the pubovaginal sling (PVS). The PVS procedure uses harvested tissue from the tough abdominal wall, called abdominal fascia. That tissue is then implanted in the shape of a hammock-like sling around the neck of the bladder and up to the abdominal wall. Since the fascial tissue comes from the patient herself, it is called "autologous," meaning tissue that comes from the same individual. The procedure rapidly rivaled the Burch colposuspension as the "gold standard" for the treatment of SUI in women.

With the advent of biologic and synthetic mesh slings, the number of traditional PVS procedures initially decreased. However, with the increasing awareness among surgeons and patients regarding the complications of vaginal synthetic mesh (including but not limited to permanent dyspareunia, life-altering pain, chronic sexual dysfunction, lifetime erosion risk, and others listed throughout this report), the PVS procedure has seen a significant resurgence. In

some regions and practices around the nation, the PVS has become the mainstay of therapy. In my own practice at a major tertiary referral medical center, I have abandoned essentially all synthetic mesh sling implantation due primarily to those complications mentioned above.

Synthetic Mesh in General Surgery

Abdominal and thoracic wall weaknesses (hernias) develop due to conditions such as birth defects, surgical complications, and radiation effects. Traditional hernia repair surgery evolved using sutures (stitches) to bring native tissue together. However, due to the inherent weaknesses of the tissues, failure was common and frequently resulted in significant pain and suffering for the patient. As a result, surgical meshes for hernia repairs were introduced in the 1950's. Since then, academic presentations, surgical reports, and journal manuscripts have described mesh-related complications such as chronic pain, abdominal wall rigidity, mesh contraction, infection, fistula formation, chronic inflammatory process, and weakness recurrence.[3]

[3] Klosterhalfen B, Junge K, Klinge W. The lightweight and large porous mesh concepts for hernia repair. Expert Rev Med Devices. 2005 Jan; 2(1):103-17. Agresta F, Baldazzi G, Ciardo et al: Lightweight partially absorbable monofilament mesh (polypropylene/poliglecaprone for TAPP inguinal hernia repair. Surg Laparosc Endosc Percutan tech 2007, 17; 91- 94. Amid PK. Classification of biomaterials and their related complications in abdominal wall hernia surgery. Hernia (1997)1:15-21. Bellon J, Honduvilla N, Jurado F et al: In vitro interaction of bacteria with polypropylene/ePTFE prostheses. Biomaterials. 2001 Jul; 22(14):2021-4. Bouikerrou M, Boulanger L, Rubod C et al: Study of the biomechanical properties of synthetic implanted in vivo. European J. Obstet & Gynecol and Repro Bio 134: (2007)262-267. Klinge U, Klosterhalfen M, Muller A et al: Shrinking of polypropylene mesh in vivo: an experiment study in dogs. European Journal of Surgery Volume 164, Issue 12, pages 965–969, December 1998. Klinge U, Klosterhalfen B, Muller M et al: Foreign body reaction to meshes used for the repair of abdominal wall hernias. Eur J Surg. 1999 Jul; 165(7):665-73. Klinge U, Klosterhalfen B, Birkenhauer V: Impact of polymer pore size on the interface scar formation in a rat model. J. Surgical Research 103, 208-214 (2002). Klosterhalfen B, Klinge W, Schumpelick V: Functional and morphological evaluation of different polypropylene- mesh modifications for abdominal wall repair. Biomaterials. 1998 Dec; 19(24):2235-46. 13 Krause H, Galloway S, Khoo S et al: Biocompatible properties of surgical mesh using an animal model. Aust N Z J Obstet Gynaecol. 2006 Feb; 46(1):42-5. Mamy L, Letouzey V, Lavigne J et al: Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. Int Urogynecol J. 2011 Jan; 22(1):47-52. Garcia M, Ruiz V, Godoy A, et al: Differences in polypropylene shrinkage depending on mesh position in an experimental study. American Journal of Surgery Vol 193, Issue 4, April 2007, p538-542. Cappelletti M, Attolini G, Cangioni G, et al. The use of mesh in abdominal wall defects. Minerva Chir. 1997 Oct; 52(10):1169-76. Klosterhalfen B, Klinge W, Hermanns B et al: Pathology of traditional surgical nets for hernia repair after long- term implantation in humans. [ABSTRACT] Chirugr 2000; 71:43-51. Seker D, Kulacoglu H. Long-term complications of mesh repairs for abdominal wall hernias. J Long Term Eff Med Implants. 2011; 21(3):205-18. Cobb W, Burns J, Peindl R et al: Textile analysis of heavyweight, mid-weight, and lightweight polypropylene mesh in a porcine ventral hernia model. J Surgical Research 136, 1-7 (2006). Pandit A, Henry J. Design of surgical meshes - an engineering perspective. Technol Health Care. 2004; 12(1):51- 65. Pierce L, Grunlan M, Hou Y et al: Biomechanical properties of synthetic

An abundance of evidence in medical literature and basic scientific data has been accumulated over the past two decades and indicates a strong and direct relationship between postoperative mesh complications and mesh design.[4] Reducing mesh-related complications demands a thorough understanding and knowledge of the chemical, physical, and synthetic characteristics of meshes and how they react inside the human body. At this point, there is a scientific consensus that synthetic meshes that are low-weight, large-pore, high porosity, monofilament, and capable of maintaining their elasticity under load have better results with fewer complications. Of all mesh characteristics, mesh stiffness, porosity, and pore size are of critical importance.

Synthetic Mesh Use in Pelvic Floor

The TVT-S was cleared for use based on its similarity to predecessor devices, like Ethicon's TVT-Retropubic and TVT-Obturator. During the TVT-R's Food and Drug Administration submission process in the late 1990's, Ethicon used the ProteGen sling as its predicate device. Introduced in April 1997 as a treatment for female SUI, the ProteGen sling was a synthetic polymer (polyester) mesh sling implant—not a polypropylene mesh as in the TVT line of products, including the TVT-S. Surgeons implanted the ProteGen polyester sling

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and biologic graft materials following long-term implantation in the rabbit abdomen and vagina. Am J Obstet Gynecol. 2009 May; 200(5):549.e1-8. Costello C, Bachman M, Grand, S, et al. Characterization of heavyweight and lightweight polypropylene prosthetic mesh explants from a single patient. Surg Innov. 2007Sep; 14(3):168-76.

[4] ETH.MESH.00869977; ETH.MESH.02589033; Robinson deposition 7-13, pg. 126-30; Klosterhalfen B, Junge K, Klinge W. The lightweight and large porous mesh concepts for hernia repair. Expert Rev Med Devices. 2005 Jan; 2(1):103-17. Agresta, F, Baldazzi G, Ciardo et al: Lightweight partially absorbable monofilament mesh (polypropylene/poliglecaprone for TAPP inguinal hernia repair. Surg Laparosc Endosc Percutan Tech 2007, 17; 91-94. Amid PK. Classification of biomaterials and their related complications in abdominal wall hernia surgery. Hernia (1997) 1:15-21. Bellon J, Honduvilla N, Jurado F et al: In vitro interaction of bacteria with polypropylene/ePTFE prostheses. Biomaterials. 2001 Jul; 22(14):2021-4. Bouikerrou M, Boulanger L, Rubod C et al: Study of the biomechanical properties of synthetic implanted in vivo. European J. Obstet & Gynecol and Repro Bio 134: (2007)262-267. Klinge U, Klosterhalfen M, Muller A et al: Shrinking of polypropylene mesh in vivo: an experiment study in dogs. European Journal of Surgery Volume 164, Issue 12, pages 965–969, December 1998. Klinge U, Klosterhalfen B, Muller M et al: Foreign body reaction to meshes used for the repair of abdominal wall hernias. Eur J Surg. 1999 Jul; 165(7):665-73. Klinge U, Klosterhalfen B, Birkenhauer V: Impact of polymer pore size on the interface scar formation in a rat model. J. Surgical Research 103, 208-214 (2002).

underneath the urethra to provide support and to reduce SUI. Unfortunately, nearly immediately following ProtoGen's launch, a large number of patients began experiencing severe complications like mesh erosion through the vaginal wall, vaginal infections, vaginal discharge, vaginal bleeding, foul odor, and dyspareunia. In January 1999, Boston Scientific Corporation, ProtoGen's manufacturer, recalled the product due to the unusually high number of complications. In the December 1999 edition of *The Journal of Urology*, a group of respected urologists from across the United States reported their findings on those complications, including a high rate of tissue erosion and urethral erosion.

In November 1998, just months before the ProtoGen recall, Ethicon brought its Tension Free Vaginal Tape (TVT) System to the US market as part of its Gynecare line. The TVT was designed as a pubourethral sling for treatement of female SUI. The device is made from polypropylene mesh (sometimes referred to by the trade name PROLENE). Despite the ProtoGen recall and the two decades worth of literature on the complications resulting from polypropylene mesh implants, the TVT remains on the market today. In fact, Ethicon has expanded the TVT line to include the TVT-O, which incorporates an obturator device to implant the mesh via an "inside-out" approach, and the TVT-S device, which is the primary focus of this report.

Ethicon received FDA approval for the TVT-S device, a single incision sling ("SIS") sometimes referred to as a "mini-sling," in 2005. The sling was composed of approximately 1.1cm x 8.0cm of polypropylene mesh (Prolene) and could be inserted via either the "Hammock approach" or the "U approach." The TVT-S device was removed from the market in 2012, after the FDA requested that Ethicon conduct postmarket surveillance studies. No such studies were performed, and the TVT-S remains off the market to this day.

B. The Polypropylene Mesh in the TVT-S Should Not Be Used in the Pelvic Floor Due to Known Complications and Hazards

Because of the defective characteristics of the TVT-S, as discussed below and throughout this report, Ethicon repeatedly fell below the standard of care in producing and marketing its device. The laser cut mesh used in the TVT-S device should not be used in the pelvic floor, because the risks of the device far outweigh the benefits of the device. The inadequacies of the Prolene mesh and the TVT-S device lead to long term complications, including but not limited to acute and chronic pelvic pain, acute and chronic vaginal pain, permanent dyspareunia, injury and pain to partner during sexual intercourse, sexual dysfunction, chronic infections, abscess formation, permanent nerve damage, defecatory dysfunction, chronic foreign body reaction, lifelong risk of erosion and extrusion, severe vaginal scarring, inability to remove the device, the need for multiple surgical interventions that carry with them significant risks of morbidity, the development of worsening incontinence and urinary dysfunction, including urinary urgency, urinary urge incontinence, and urinary retention. As such, the TVT-S device is not suitable as a permanent implant.

1. <u>The mesh in the TVT-S is not inert and degrades</u>

As polypropylene has been used in surgery for over 50 years as a suture material, Prolene mesh, like the kind used in the TVT-S, was marketed by Ethicon as inert. However, many published studies and internal Ethicon documents show that the mesh is not inert and does in fact degrade.[5] In 1987, for example, Ethicon tested samples of explanted Prolene mesh made from

[5] ETH. MESH.08315783; ETH.MESH.02589033; Robinson Deposition 7-13, p120, 129-130; Hinoul Deposition 4-5, p165-170; Kirkemo Deposition 4-18, p138; 84 Klinge U, Klosterhalfen B, Muller M et al: Foreign body reaction to meshes used for the repair of abdominal wall hernias. Eur J Surg. 1999 Jul;165(7):665-73. Klinge U, Klosterhalfen B, Birkenhauer V: Impact of polymer pore size on the interface scar formation in a rat model. J. Surgical Research 103, 208-214 (2002). Klinge U, Klosterhalfen M, Muller A et al: Shrinking of polypropylene mesh in vivo: an experiment study in dogs. European Journal of Surgery Volume 164, Issue 12, pages 965–969, December 1998.; Klosterhalfen B, Klinge W, Schumpelick V: Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair. Biomaterials. 1998 Dec;19(24):2235-46.;

the same material as the TVT-S mesh.[6] After 8 years of implantation, the testing showed that the mesh was severely cracked. In 1992, Ethicon completed a study where Prolene sutures were implanted in beagle dogs for up to seven years. These sutures were removed from the dogs and examined by Ethicon's own scientists, who found surface degradation in many of the samples after 7 years of implantation.[7] Ethicon scientist and corporate spokesperson, Thomas Barbolt, agreed that surface degradation can occur with Prolene mesh, and that this fact was confirmed by the Ethicon studies.[8]

Further evidence that polypropylene mesh degrades over time was provided in 1998 by the publication of the Mary article, who studied the phenomenon of mesh degradation, and concluded the process of polypropylene cooling, where the polypropylene strand cools first on the inside and then on the outside can make the strand more susceptible to degradation on the outside.[9] In 2007, Costello et al., reported that polypropylene is more susceptible to degradation due to oxidation caused by inflammatory response.[10] Using Scanning Electron Microscopy (SEM), degradation could be seen in polypropylene in the form of cracks and peeling.

Dr. Donald Ostergard, urogynecologist and founder of AUGS, created a presentation titled "Polypropylene is Not Inert in the Human Body" in which he described degradation of in vivo

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Klosterhalfen B, Klinge W, Hermanns B et al: Pathology of traditional surgical nets for hernia repair after long-term implantation in humans. [ABSTRACT] Chirugr 2000;71:43-51.; Klosterhalfen B, Junge K, Klinge W. The lightweight and large porous mesh concepts for hernia repair. Expert Rev Med Devices. 2005 Jan;2(1):103-17. Clave A, Yahi H, Hammou J, et al. Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 patients. Int Urogynecol J. 2010 Mar;21(3):261-70. Klinge et al The Ideal Mesh Klosterhalfen et al: Retrieval study at 623 human mesh explants made of polypropylene.

[6] ETH.MESH.12831407

[7] ETH.MESH.05453719

[8] Barbolt deposition, 1-14, p409, 516-517

[9] Mary C, Marios Y, King MW, et al. Comparison of thein vivo behavior of polyvinylidene fluoride and polypropylene sutures used in vascular sugary. ASAIO Journal 44, 1998, 199–206.

[10] Costello C, Bachman M, Grand S, et al. Characterization of heavyweight and lightweight polypropylene prostethic mesh explants from a single patient. Surg Innov. 2007 Sep; 14(3):168-76.

polypropylene.[11] Dr. Ostergard concluded that Prolene mesh degradation occurs by oxidation. He further concluded that a large surface area, such a piece of surgical mesh, in contrast to a suture, incites more inflammation and results in more oxidation since more macrophages are present. These macrophages then secrete hydrogen peroxide and hypochlorous acid to oxidize the mesh, which can cause the mesh to become brittle and to crack. As discussed below, these changes cause complications to patients due to the increased inflammatory response.

In a 2010 article by Clave et al., 100 pelvic floor explants were analyzed.[12] Results showed that *all types of polypropylene implants exhibited degradation*. "Mesh damage included superficial degradation, which appeared as a peeling of the fiber surface, transverse cracks in the implant threads, significant cracks with disintegrated surfaces and partially detached material, and superficial or deep flaking." The authors concluded that their research directly "contradicts" the idea that polypropylene is "an inert material." The authors further stated that "[f]or transvaginal surgery, clinical experience indicates the use of low density, large pore implants knitted from a monofilament to facilitate tissue integration, and decrease the inflammatory response…. [N]ot all types of PP implants degraded equally." The authors hypothesized that in vivo oxidation of polypropylene implants, "as reported in the literature," oxidation due to free radical attack, or "septic environment and large detachments of the vaginal approach resulting in collection and bruising hematoma [supporting] both the accumulation of fatty acids and an increased risk of infection," could contribute to degradation. It should be noted that the lead author, Henri Clave, holds an educational position for Ethicon Europe. Two other authors had ties to Sofradim and Covidien.

[11] "Polypropylene is Not Inert in the Human Body" Presentation by Donald R. Ostergard

[12] Clave A, Yahi H, Hammou J, et al. Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 patients. Int Urogynecol J. 2010 Mar;21(3):261-70.

Later, in 2013, the Wood study found that polypropylene explanted from a patient showed significant oxidation of the material, and concluded that polypropylene will degrade in an oxidizing environment, such as human tissue undergoing a foreign body response.[13] In 2015, seven explants from "Gynemesh, TVT, TOT, SPARC and minisling" were explanted 4-7 years after implantation. Comparison of SEM images for explant samples with control pristine samples revealed extensive surface degradation and the formation of surface cracks in the samples, demonstrating that polypropylene fibers from mid-urethral slings are not inert over time.[14] Other authors and studies have demonstrated similar results with polypropylene in general.[15] Dr. Iakovlev has published numerous articles showing and explaining the degradation and surface cracking of polypropylene explants using histological and transmission electron microscopy approaches.[16]

The fact that polypropylene cracks and breaks inside the human body is a serious concern. As polypropylene degrades, the human body's inflammatory response increases and intensifies. The abraded fiber surface increases the surface area of the mesh, providing multiple areas that can effectively harbor bacteria and become brittle, which lead to an increased risk of an

[13] Wood, et. al. Materials characterization and histological analysis of explanted polypropylene, PTFE, and PET hernia meshes from an individual patient. J Mater Sci: 24:1113-1122 (2013).
[14] K Tzartzeva, D Lingam, M Baniasadi, M Minary-Jolandan, P Zimmern. Neurology and Urodynamics. 2014 33 (6), 820-822.
[15] Iakovlev, et al., Pathology of Explanted Transvaginal Meshes. Intl . Science Index Vol. 8 No. 9 (2014); Martin, MK Gupta, JM Page, F Yu, JM Davidson, SA Guelcher, CL Duvall. Synthesis of a Porous, Biocompatible Tissue Engineering Scaffold Selectively Degraded by Cell-Generated Reactive Oxygen Species. Biomaterials 35(12):3766-76, 2014; AE Hafeman, KJ Zienkiewicz, AL Zachman, HJ Sung, LB Nanney, JM Davidson, SA Guelcher. Characterization of degradation mechanisms of biodegradable lysine-derived aliphatic polyurethanes. Biomaterials 32(2):419-29, 2011.
[16] Iakovlev V, Guelcher S, Bendavid R. In Vivo Degradation of Surgical Polypropylene Meshes: A Finding Overlooked for Decades. Virchows Archiv 2014, 463(1): 35; Iakovlev V, Guelcher S, Bendavid R. In Vivo Degradation of Surgical Polypropylene Meshes: A Finding Overlooked for Decades. Virchows Archiv 2014, 463(1):35.

enhanced and chronic inflammatory response, severe scarring, and chronic infections due to bacterial proliferation at the mesh surface.[17]

As stated, Ethicon knew this information decades before the launch of the TVT-S. There are Ethicon studies dating back as far as 1983, using methods nearly identical to Dr. Iakovlev's, showing in vivo degradation of the Prolene polypropylene material.[18] Ethicon conducted additional studies in 1985 (dog study) and in 1987 (human explant), both showing in vivo degradation and cracking of the polypropylene materials.[19] Eventually, Ethicon had its meshes reviewed by an outside consulting company, which found that Ethicon meshes degrade and that the process starts within days of implant.[20]

Remarkably, Ethicon's IFU still claims that the mesh in the TVT-S, "is not absorbed, nor is it subject to degradation or weakening by the action of enzymes."[21] Such a statement is reckless and knowingly false, putting patients at risk for serious complications and leaving physicians without knowledge critical to making informed decisions. It is my opinion, to a reasonable degree of medical and scientific certainty, that polypropylene degrades in the human body, causing complications including but not limited to acute and chronic pelvic pain, acute and chronic vaginal pain, permanent dyspareunia, injury and pain to partner during sexual intercourse, sexual dysfunction, chronic infections, abscess formation, permanent nerve damage, defecatory dysfunction, chronic foreign body reaction, lifelong risk of erosion and extrusion, severe vaginal scarring, inability to remove the device, the need for multiple surgical interventions that carry with them significant risks of morbidity, the development of worsening

[17] Mamy L, Letouzey V, Lavigne J et al: Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. Int Urogynecol J. 2011 Jan;22(1):47-52.
[18] ETH.MESH.15955438
[19] ETH.MESH.00004755; ETH.MESH.11336474; ETH.MESH.13334286
[20] ETH.MESH.07192929
[21] ETH.MESH.02340568

incontinence and urinary dysfunction, including urinary urgency, urinary urge incontinence, and urinary retention. Undoubtedly, Ethicon should have informed doctors of the known fact of degradation, and the company should have conducted clinical testing relating to the impact of polypropylene degradation in the pelvic floor. Such testing would have confirmed the fact that polypropylene is not suitable for permanent implantation in the human body.

2. The MSDS for the Prolene mesh states not to use with strong oxiders like peroxides, which can be abundantly found in the vagina

The fact that polypropylene degrades in vivo is especially problematic given the naturally occurring oxidizers in the pelvic floor. Ethicon was warned in advance of the potential consequences of permanently implanting polypropylene in the female body.

The polypropylene mesh in the TVT-S is made from plastic pellets supplied by Sunoco, a petrochemical company. Included with these plastic pellets is a material safety data sheet ("MSDS"), a public document intended to provide those handling or working with the product instructions and information on how to handle the substance in a safe matter, and, more generally, intended to describe the safety (or lack thereof) of a particular product.[22] I have reviewed a number of data sheets for the resin used by various manufacturers to produce pelvic mesh products.

The MSDS for the TVT-S polypropylene states:

> **INCOMPATIBILITY**
>
> The following materials are incompatible with this product: Strong oxidizers such as chlorine, peroxides, chromates, nitric acid, perchlorates, concentrated oxygen, sodium hypochlorite, calcium hypochlorite and permanganates. Chlorine; Nitric acid. [23]

[22] Weisberg deposition 8-13, p909.
[23] ETH.MESH.02026591

Although the resin used to make the TVT-S mesh is also used in number of other Ethicon products, including Prolene hernia mesh and Prolene sutures, this warning is particularly important as it applies to the TVT-S mesh, as the TVT-S mesh is intended to be placed in the vagina, which is a ready and natural source of peroxides, a strong oxidizer. Peroxides are regularly and naturally produced by a woman's body. By contrast, the Prolene hernia mesh is not intended to be placed in vagina. Further, TVT-S mesh contains approximately 1,000 times more plastic material than a Prolene suture, so the clinical effects of oxidization would be markedly different between a suture and the TVT-S mesh.

This warning in the Prolene MSDS should have triggered an investigation into the effects of naturally occurring oxidizers on the TVT mesh prior to Ethicon's marketing of the device (and certainly prior to the TVT-S, developed years later), particularly with regard to oxidation and degradation of the mesh, as well as inflammation caused the presence of these naturally occurring substances. At the very least, Ethicon should have passed this warning along to surgeons and patients using Prolene mesh, so that they could make an informed choice about whether or not to use the device. However, no such warning regarding the TVT-S mesh's incompatibility with strong oxidizers has been communicated, and Ethicon never did studies specifically examining the clinical effect of these natural oxidizers on the TVT-S mesh. It is my opinion to a reasonable degree of medical certainty that Ethicon has failed in its duty as a reasonable medical device manufacturer by failing to include this warning in the IFU, and by failing to adequately study the clinical effects of the vagina's natural oxidizers on Prolene mesh.

Disturbingly, the MSDS also states that subcutaneous implantation of polypropylene led to local sarcomas in lab rats. The carcinogenic properties of polypropylene also should have been

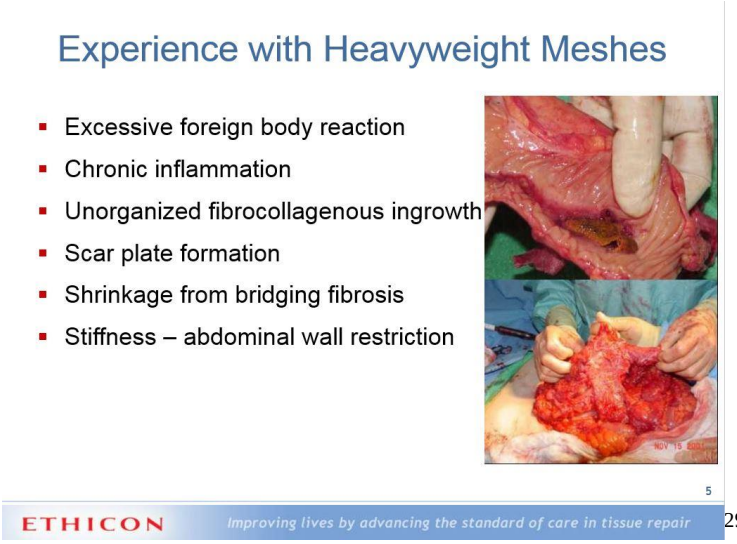
disclosed to doctors, and Ethicon should have done follow-up studies relating to Prolene and cancer. No such disclosure or studies occurred.[24]

3. The TVT-S mesh is heavy with small pores, causing increased tissue response, chronic inflammatory response, contraction and shrinkage of the mesh, fibrotic bridging and scar plate formation

Inflammation and Chronic Foreign Body Response

As stated, the Prolene mesh used in devices like the TVT-S is the same mesh Ethicon has used for decades. Ethicon itself refers to the Prolene mesh as "old."[25] Importantly, Ethicon scientists have known for more than 16 years that heavyweight, small pore meshes, like the Prolene mesh comprising the TVT-S, are associated with excessive foreign body reaction, chronic inflammation, bridging fibrosis, scar plate formation, and consequential shrinkage of the mesh.[26] Ethicon knew that the mesh used in the TVT-S is heavyweight and has small pores.[27] Ethicon also knew the need for lighter weight materials, which elicit a lower inflammatory response in the human body.[28]

[24] Robinson deposition 9-13, p1105-1115
[25] ETH.MESH.10633520 -22
[26] ETH.MESH.05479411; Klinge U., Klosterhalfen B., Birkenhauer V., Junge K., Conze J., and Schumpelick V., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model; Cobb W, Kercher K, Heniford T. The Argument for Lightweight Polyropylene Mesh in Hernia Repair. Surgical Innovation. 2005; 12(1):T1-T7; Cobb, W., et al. Textile Analysis of Heavyweight, Mid-Weight, and Lightweight Polypropylene Mesh in a Porcine Ventral Hernia Model. Journal of Surgical Research 136, 1-7 (2006); Klinge U, Klosterhalfen B, Muller M, Ottinger A, Schumpelick V. Shrinking of Polypropylene Mesh in vivo: An Experimental Study in Dogs. Eur J Surg. 1998: 164; 965-969; Klosterhalfen, B., Junge, K., Klinge, U.The lightweight and large porous mesh concept for hernia repair. Expert Rev. Med. Devices. 2005; 2(1)
[27] ETH.MESH.05479411; ETH.MESH.05479535. Cobb et. al., The Argument for Lightweight Polypropylene Mesh in Hernia Repair, Deposition of Joerg Holste, July 29, 2013 40:12-15, Hellhammer Deposition, 11-13, p151.
[28] ETH.MESH.01203957; ETH.MESH.05479411; Trial Testimony of Piet Hinoul, *Batiste*, March 27, 2014 afternoon, p73.



[29]

In fact, Ethicon developed lighter weigh materials for use elsewhere in the human body, including the pelvic floor.[30] However, Ethicon continued to use the heavyweight, small pore Prolene mesh, originally developed in 1974 for use in hernia surgery, for its TVT-S device used for SUI.[31] This is true despite the fact that Ethicon knows the heavyweight, small pore meshes cause a greater inflammatory response than lightweight, large pore meshes regardless of where the mesh is located in the human body.[32]

To be sure, the decision to continue using Prolene, despite known complications and the availability of lighter weight, smaller pore mesh, was financial. As Dr. Arnaud put it, Ethicon "want[ed] to be very careful with any modifications of our tape since a change in the mesh would obsolete all the long term clinical results." [33]

The decision to continue using decades-old mesh has had serious ramifications for patients. The body's foreign body response to mesh can cause a chronic inflammatory reaction, leading to excessive scarring in and around the mesh, as well as potentially debilitating pain. The

[29] ETH.MESH.05479411
[30] Holste deposition 7-13, p51-53.
[31] ETH.MESH.04941016; HMESH_ETH_02030355; ETH.MESH.02340568-ETH.MESH.02340590.
[32] Holste deposition 7-13, p95
[33] ETH.MESH.03911107; Hellhammer deposition, 9-13; Arnaud deposition 7-13, p36-37.

degree of this reaction is directly related to the weight and pore size of the mesh device.[34] Ethicon knew that clinical data shows more chronic pain with heavyweight meshes such as the TVT-S mesh, than with lightweight, partially absorbable meshes. One study found that heavyweight meshes with small pores had to be explanted due to chronic pain more frequently than lightweight meshes with large pores.[35] Indeed, Ethicon's own medical director has stated that the presence of the Prolene mesh can be responsible for chronic pain syndrome in the patient.[36]

Shrinkage and Contraction

Further, the foreign body reaction, exacerbated by the heavyweight and small pore construction, is chronic, and this chronic inflammation and reaction can lead to mesh contraction and shrinkage.[37] Most studies show less shrinkage in lighter weight meshes, and pore size is one of the most important factors regarding mesh shrinkage.[38] Ethicon knew that all polypropylene meshes experience a 20-50% reduction in their initial size following implantation in the body.[39] Ethicon's own medical director knew that the Prolene mesh can shrink, and generally believed the TVT mesh would shrink approximately 30% post implantation.[40] The mesh contraction and shrinkage can increase the degree of foreign body reaction and mesh degradation, in turn

[34] Hinoul deposition 4-12, p99; ETH.MESH.08315782; Trial Testimony Piet Hinoul, *Batiste*, March 27, 2014 afternoon, p27; ETH.MESH.05916450
[35] Klostherhalfen,B, Junge, K, Klinge, U, The lightweight and large porous mesh concept for hernia repair. Expert Rev. Med. Devices, 2005 2(1)
[36] ETH.MESH.01202102
[37] Vailhe deposition 6-13, p838.
[38] ETH.MESH.02316781; Cobb W, Kercher K, Heniford T. The Argument for Lightweight Polyropylene Mesh in Hernia Repair. Surgical Innovation. 2005, 12(1):T1-T7.
[39] Cobb W, Kercher K, Heniford T. The Argument for Lightweight Polyropylene Mesh in Hernia Repair. Surgical Innovation. 2005, 12(1):T1-T7.
[40] ETH.MESH.03910418

increasing the degree of pelvic pain and pelvic floor dysfunction, such as dyspareunia and difficulty urinating.[41]

Additionally, a recent study has shown that mesh shrinkage is progressive, with a linear evolution of the contraction rate over time, indicating that mesh contraction continues in the patient's body indefinitely into the future.[42] Vaginal mesh contraction can result in vaginal fibrosis, infection, chronic vaginal pain, chronic pelvic pain, vaginal shortening, vaginal narrowing, vaginal extrusion, adjacent organ erosion, and dyspareunia. Feiner and Maher evaluated 17 women with vaginal mesh contraction to demonstrate that the mesh caused the condition. The patients' presenting complaints included severe vaginal pain, dyspareunia, and focal tenderness over contracted portions of mesh on vaginal examination, mesh erosion, vaginal tightness, and vaginal shortening. The patients underwent surgical intervention with mobilization of mesh from underlying tissue, division of fixation arms of the central graft, and excision of contracted mesh. Fifteen of 17 (88%) patients reported a substantial reduction in vaginal pain following explanation, while none of 11 (64%) reported substantial reduction in dyspareunia. However, despite Feiner's relative success with mesh explanation, the adverse effects of transvaginal mesh contraction caused permanent life-altering sequelae in 22-46% of patients in this study.[43] I personally see this type of permanent life-altering sequelae in my daily practice in patients I treat for severe complications related to mesh slings, including Ethicon's TVT-S device.

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[41] De Tayrac, et. al. Garcia M, Ruiz V, Godoy A, et al: Differences in polypropylene shrinkage depending on mesh position in an experimental study. American Journal of Surgery Vol 193, Issue 4, April 2007, p538-542.

[42] Mamy L, Letouzey V, Lavigne J et al: Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. Int Urogynecol J. 2011 Jan;22(1):47-52.

[43] Feiner B, Maher C. Vaginal mesh contraction: definition, clinical presentation, and management. Obstet Gynecol. 2010 Feb;115(2 Pt 1):325-30.; Foon R, Toozs-Hobson P, Latthe P. Adjuvant materials in anterior vaginal wall prolapse surgery: a systematic review of effectiveness and complications. Int Urogynecol J Pelvic Floor Dysfunct. 2008 Dec;19(12):1697-706.

Scarring

Polypropylene induces a rapid and acute inflammatory response and strong scar formation. Heavyweight meshes with small pores, such as the Prolene mesh in the TVT-S, induce an intense, chronic foreign body reaction with intensified fibrotic bridging and scar formation.[44] Eventually, the small pores are overwhelmed by the formation of scar tissue, and the entire mesh sling can become encased in a scar plate. This scar plate prevents proper tissue ingrowth.

An increased foreign body reaction with a chronic inflammatory response, followed by the formation of a rigid scar plate, are the primary reasons for the shrinkage and contraction of mesh, which in turn leads to complications including pain and permanent nerve damage.[45] Decreasing the weight of mesh reduces both shrinkage and the inflammatory response. A pore size of at least 1 mm in all directions is needed to prevent the fibrotic bridging and scar plate formation.[46] Despite Ethicon's claims to the contrary, the mesh in the TVT-S has a pore size that is much smaller than 1mm after implantation.[47]

[44] ETH.MESH.02316781; ETH.MESH.01218361
[45] ETH.MESH.01218361
[46] ETH.MESH.01785259; ETH.MESH.02316781; ETH.MESH.02148431; ETH.MESH.01218361; Klosterhalfen B, Junge K, Klinge U. The lightweight and large porous mesh concepts for hernia repair. Expert Rev Med Devices. 2005 Jan;2(1):103-17; Batke deposition 8-12, p113-114, 118-120, 172-174;Hellhammer deposition 9-13, p403-407; Holste deposition 7-13, p51-53; Holste Deposition 12-12, p89-90; Semin Immunopathol (2011) 33:235–243 - a Scar net formation following large pore (~3 mm) and b scar plate formation following small-pore (~0.3 mm) mesh implantation; Arnaud deposition 9-13, p756-757; ETH.MESH.03021946; ETH.MESH.02587926; ETH.MESH.01752532; ETH.MESH.01785259; ETH.MESH.04941016
[47] ETH.MESH.08315782

Table 1 - Characteristics of Various mesh implants

MESH	Unit Weight (mg/cm2) permanent component	Burst Strength, psi	Maximum Pore Size, mm
PROLENE* Polypropylene Mesh	7.6	234	<1
GYNECARE GYNEMESH* PS Nonabsorbable (PROLENE* Soft Mesh)	4.5	116	2.5
MERSILENE* Polyester Fiber Mesh	3.3	83	<1
VYPRO Mesh	2.5	71 (pre-absorption 90)	4.5
VYPROII Mesh	3.5		3-4
ULTRAPRO* Partially Absorbable Mesh (GYNECARE GYNEMESH M* Mesh)	2.8	90 (pre-absorption 135)	5.0

[48]

The fact that the pore size of the TVT-S is not greater than 1mm in all directions prevents proper tissue integration, which can reasonably be expected to result in the development of a rigid scar plate, leading to, among other things, the potential for increased erosion, pain, nerve entrapment, vaginal shortening, SUI recurrence, urethral obstruction, and dyspareunia.[49] As with other risks, it is well-documented that Ethicon also knew the design of its Prolene mesh could lead to a severe foreign body reaction, excessive scarring and fibrotic bridging, and mesh shrinkage.[50] Nonetheless, Ethicon failed to disclose its own findings, leaving doctors and patients in the dark.

4. Ethicon's Prolene mesh tested positive for cytotoxicity

Cytotoxicity is the quality of being toxic to cells. If a woman's tissues or organs are exposed to a cytotoxic substance, the cells may experience necrosis and die rapidly, or they may undergo a form of controlled cell death known as apoptosis. It is my understanding that it is

[48] ETH.MESH.08315782

[49] Klinge U, Otto J, Muhl T. High Structural Stability of Textile Implants Prevents Pore Collapse and Preserves Effective Porosity at Strain. BioMed Research International. 2015, 953209.

[50] ETH.MESH.05920616; ETH.MESH.04037600; ETH.MESH.05920616; ETH.MESH.05585033; ETH.MESH.05446127; ETH.MESH.05475773; ETH.MESH.04015102; ETH.MESH.04037600; Batke deposition 8-13, p87-88, 113-114, 257-259; Holste deposition 7-13, p51-57; Vailhe deposition 6-13, 182-185.

common for medical devices to be subjected to cytotoxicity testing before they are marketed to doctors and patients.

In support of its application to market the TVT (and then the TVT-S) in the United States, Ethicon did not perform any controlled clinical studies to determine the cytotoxic potential of the TVT, but instead determined that the "long term clinical experience with PROLENE mesh indicated the [prior] cytotoxicity testing would be sufficient to support the biocompatibility of this [mesh] component."[51] Of course, prior to marketing the TVT device, the Prolene mesh had primarily been used in abdominal hernia repair, and had never before been specifically indicated for use in vaginal tissues. As a result, Ethicon's conclusion that no new clinical or animal studies were needed to evaluate the cytotoxic potential of the TVT mesh is questionable at best. In fact, to this day, I am not aware of any long-term studies undertaken by Ethicon to determine whether or not the TVT mesh is clinically cytotoxic in women.[52]

Notably, the 2004 Wang study reported a defective healing rate of 2.2% in a series of 670 patients, and a persistent defective healing rate of 1%, which is suggestive of cytotoxicity.[53] Although this study was not published until 2004, Ethicon had been advised that Dr. Wang had experienced 25 erosions from the TVT mesh, which he suspected was due to the body's rejection of the Prolene mesh in 2002.[54]

The initial Cytotoxicity testing of the TVT prototype device was conducted in March of 1997, and tested all components of the device together for a period of 24 hours. The results of this test indicated the mesh was severely cytotoxic.[55] Ethicon's own Scotland lab performed

[51] ETH.MESH.08476210
[52] Robinson deposition 9-13, p1101-1102.
[53] Wang AC, et. al. A histologic and immunohistochemical analysis of defective vaginal tape healing after continence taping procedures: A prospective case-controlled pilot study. American Journal of Obstetrics & Gynecology. 2004;191(6):1868–1874.
[54] ETH.MESH.03736989; ETH.MESH.00409674
[55] ETH.MESH.06851860

follow-up testing, this time testing the needle, heat shrinking tube, sheath, and polypropylene mesh separately. In this test, the polypropylene mesh in the TVT again tested positive for marked cytotoxicity. Ethicon did a third and final test in July of 1997, which finally provided a non-cytotoxic result for the polypropylene mesh. Ethicon relied on the results of this final, July 1997 test in support of its application to market the TVT device, and did not report the two prior positive cytotoxic test results to the FDA, surgeons, or the public.

Ethicon's own Worldwide Medical Director from 2005-2010 was not aware of these positive tests during his tenure.[56] Notably, even the 1997 ISO elution testing showed that the polypropylene mesh in the TVT was moderate to severely cytotoxic, while the ISO agarose diffusion testing showed the mesh was non-cytotoxic. Despite the positive ISO elution testing, and the two previous tests showing the mesh was cytotoxic, Ethicon concluded that "the long history of safe clinical use of polypropylene as a mesh and suture products suggests strongly that the material is inherently biocompatible, and the potential cytotoxicity observed is self-limiting and minimal when compared to the implantation procedure itself." [57]

It is my opinion that based on the 3 positive cytotoxic test results, Ethicon failed in its duty as a reasonable medical device manufacturer by not conducting long-term studies to assess the cytotoxic potential of the TVT mesh, and thus the TVT-S mesh, prior to marketing the device in women. This is particularly true in light of the fact that the Prolene mesh had never before been indicated specifically for use in vaginal tissues, and that there was only limited, short term data for 200 patients on a prototype device available at the time the device was first sold in the United States. In addition, the reports of 25 tape erosions from Dr. Wang in 2002 should have

[56] Robinson deposition 9-13, p1094-1095.
[57] ETH.MESH.08476210

triggered an additional testing and assessment of the cytotoxic potential of the TVT mesh, but no additional cytotoxic testing was done as a result of these reports.

Although Ethicon claims to have conducted additional cytotoxicity testing prior to FDA approval of the TVT-S, this does not explain the prior positive tests relating to the TVT.[58] And, given the company's history of selectively releasing studies and tests, the 510(k) application hardly puts to rest concerns about Prolene's cytotoxic nature.[59] I have personally seen the clinical effects of the cytotoxic potential of Prolene mesh in my practice. When I have removed Prolene TVT-S mesh from a patient with a mesh erosion, the tissue surrounding the mesh frequently shows evidence of necrosis and cell death. This type of necrosis is typically due to either toxins, infections, trauma, or some combination of the three.

C. The TVT-S Should Not Be Used in the Pelvic Floor Due to its Defective Design

1. <u>The TVT-S mesh is laser cut, resulting in a stiffer product and higher incidence of complications</u>

Originally, Ethicon produced its line of TVT products by mechanically cutting the Prolene mesh. With the introduction of TVT-S, the company decided to use lasers to cut the mesh instead

[58] ETH.MESH.01311841

[59] Ethicon has never conducted a long-term randomized controlled trial with safety as a primary endpoint. (Trial Testimony of Piet Hinoul, *Batiste*, March 27, 2014 afternoon, p57.) In addition, to my knowledge, with respect to studies performed by persons outside of Ethicon, very few are long term randomized controlled studies and none include a primary endpoint of safety. (Robinson deposition 9-13, p977.) There have also been recent studies that suggest that the studies assessing risks of synthetic mid-urethral slings to date are poor and that long term data or evidence lags behind shorter-term studies. (Ford, et. al. Mid-urethral sling operations for stress urinary incontinence in women (review). The Cochrane Library (2015); Blaivas, et. al. Safety considerations for synthetic sling surgery. Nat. Rev. Urol. 2015:12 481-509.) Ethicon routinely relies and promotes its products based on long-term data from the original Ulmsten (and later Nilsson) data and studies. However, the studies lack significant data and fail to consider or inquire about many safety risks on the original patient cohort. The Ulmsten/Nilsson data is also biased in that Dr. Ulmsten had financial incentives to obtain certain results with his original studies and received numerous payments, consulting agreements, and royalties related to the TVT and his involvement with Ethicon. (ETH.MESH.03259439; Robinson deposition 9-13, p214-219.)

of machines. According to Ethicon, the change to lasers meant that the new mesh "was about three times stiffer than the machine-cut TVT mesh."[60]

Predictably, Ethicon conducted no clinical testing on the significance between mechanical cut and laser cut mesh.[61] According to internal Ethicon documents, the company tried to stress that there was nothing clinically significant or "new" about laser cut mesh, in part because "[I]f our results are as we claim [then] why are we changing the mesh with no clinical data?".[62]

Most importantly, the stiffness of the laser-cut mesh can result in additional complications for the patient, as compared to mechanically cut mesh. According to multiple Ethicon employees, for example, stiffer or more rigid mesh can result in a higher incidence of erosion, sexual dysfunction, and voiding dysfunction.[63] A study by Neuman found much higher rates of dyspareunia, attributable to the stiffness of the mesh.[64] In my own practice, I have likewise noticed the more rigid quality of mechanically cut mesh and have identified these types of complications following implantation.

2. <u>The TVT-S design is flawed because there is no way to properly tension the device</u>

Proper tensioning of the TVT-S device is critical to ensure that the device is both successful in its intended use to cure stress urinary incontinence and to prevent complications. However, the design of the TVT-S device is flawed because Ethicon cannot properly determine and/or instruct surgeons on the proper placement of the device and, in fact, Ethicon provides nonsensical or misleading instructions on tensioning in its Instructions for Use ("IFU"). It is

[60] ETH.MESH.01809080; Moalli P. A., Papas N., Menefee S., Albo M., Meyn L., Abramowitch S. D. Tensile properties of five commonly used mid-urethral slings relative to the TVT. International Urogynecology Journal and Pelvic Floor Dysfunction. 2008;19(5):655–663.
[61] ETH.MESH.01221735; ETH.MESH.03941617
[62] ETH.MESH.06040171
[63] ETH.MESH.00294195; ETH.MESH.00271641; ETH.MESH.00328895; ETH.MESH.03916716; ETH.MESH.01782949
[64] Neuman M. Transobturator vs. Single-Incision Suburethral Mini-slings for Treatment of Female Stress Urinary Incontinence: Early Postoperative Pain and 3-year Follow Up. J Min. Invas. Gynecol 2011 Nov-Dec;18(6):769-73.

known that improper tensioning of slings can lead to failure of the procedure, urinary retention, and well as urinary obstruction. The TVT-S IFU itself states that "[o]ver-correction, i.e., too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction," and that "[u]nder-correction . . . may result in incomplete or no relief from urinary incontinence."[65] Too much tension on the mesh can also lead to vaginal or urethral erosions, which the IFU does not mention.[66]

To begin with, the IFU repeatedly refers to the TVT-S as "tension free." And yet the IFU warns that "over-correction, i.e., too much tension" can result in complications. Presumably, if the tape is "tension free," the IFU should state that *any* tension can result in complications, not merely the vague phrase "too much." Worse, the IFU warns of the possibility of "under-correction," which is presumably impossible with a device that is truly tension free. The IFU informs surgeons to "[e]nsure that the tape is placed with no tension."

I am not alone in my confusion regarding the tensioning of the TVT-S. Key Opinion Leader Malcolm Frazer reported to Ethicon in November 2007 that "the [TVT-S] IFU is fundamentally misleading. Tension-free, tension-less and placement with no tension are complete misnomers."[67] Professor Frazer also noted that Ethicon "is now suggesting [outside the IFU] that [the TVT-S] should be much tighter than [the IFU] states, because you assume [the mesh] or tissues may loosen." (Other Ethicon documents include similar suggestions regarding additional tension.)[68] He further stated that Ethicon had released "inadequate" and "contradictory or confusing statements on tension."

[65] ETH.MESH.02340589
[66] ETH.MESH.05529653; ETH.MESH.0016113; ETH.MESH.05529274; ETH.MESH.04044797
[67] ETH.MESH.00311792
[68] ETH.MESH.01782949

The IFU also instructs that the procedure may be performed under general anesthesia. However, the IFU notes that the positioning of the "tension-free tape" should be considered by "cough test or other [undescribed] means." It is impossible to perform a cough test with a patient under general anesthesia, and Ethicon quite literally provides no guidance for assessing the placement and tensioning of the TVT-S in that situation.

Ethicon's lack of guidance on tensioning the TVT-S is a repeat of the company's approach to the original TVT. For example, the fact that the cough test was necessary to properly tension the mesh was noted by Dr. Ulmsten in his original 1996 publication on the TVT, as well as the co-inventor of the TVT, professor Nilsson, who noted that there was a 15% difference in success rates between patients treated with the TVT under local anesthesia with a cough test, and patients under general anesthesia, where no cough test was possible.[69] Despite being aware of this concern, Ethicon launched the TVT with an IFU that informed physicians that the procedure could be performed under general or local anesthesia, yet did not inform physicians that the success rate was much greater if performed under local anesthesia with a cough test. In 2001, Ethicon medical directors recognized the need to have a standardized approach for tensioning the TVT and began work on a product which would avoid excessive tension. This product was never completed, and Ethicon never addressed how to instruct surgeons to properly tension the mesh. Ethicon employees have acknowledged that the TVT line has never truly been tension free, despite years of marketing it as such, and that they cannot accurately describe how to tension the mesh.[70]

Further, the fact that the mesh undergoes changes to its physical characteristics, which may vary from patient to patient, within days of implantation and then continuously throughout

[69] ETH.MESH.0404851
[70] ETH.MESH.01784428; ETH.MESH.06861473

its time in the human body, means that "proper" tensioning is likely impossible. Ethicon failed to consider or inform physicians that the mesh could shrink from 30-50% once the TVT-S was placed, which obviously affects the final placement and tensioning of the mesh.[71] (Actual shrinkage rates vary based on the individual patient, type of mesh, and location of mesh in the body.)

In sum, Ethicon's instructions leave the physician with no clear, articulable standard on how to avoid serious adverse reactions like urinary retention or urinary obstruction. Since it is generally impossible to adjust the tensioning more than 24 hours after an operation due to tissue ingrowth, a re-operation surgery is generally required to correct improper tensioning. Therefore, it is particularly important to describe the proper tensioning of the device as part of the product information.

It is my opinion to a reasonable degree of medical certainty that Ethicon has failed in its duty as a reasonable medical device manufacturer by not developing and articulating clear and accurate instructions to surgeons on how to tension the mesh, rendering the device defective. It is also my opinion to a reasonable degree of medical certainty that Ethicon cannot develop and articulate clear and accurate instructions on how to properly tension the mesh as long as defects of heavyweight, small pore, polypropylene mesh exist, as those defects create too many variations in the tensioning of the device to be overcome by instructions, no matter how well designed and articulated they may be.

3. The TVT-S is defectively designed in its insertion instruments and technique

Like the TVT and TVT-O, the design of the TVT-S is inherently defective given its use of Prolene mesh, which degrades and deforms in the pelvic floor, leading to serious

[71] ETH.MESH.03917375

complications as explained above. The TVT-S, moreover, was in fact designed even more poorly than its predicate devices.

Ethicon received FDA approval for the TVT-S under the 510(k) approval process, which is meant for devices that are "substantially equivalent" to a previously approved device. Ethicon asserted that the TVT-S was substantially equivalent to the TVT and TVT-O, but the reality is that the TVT-S is quite different, particularly as far as the implantation technique. The inserters were new,[72] and the procedure, including the "hammock" and "U" methods, was new.[73] As stated previously, the mesh was also the first to be laser cut, which alters the physical characteristics of the mesh as compared to the mechanical cutting utilized for the TVT. As Malcom Frazer put it: the TVT Secur is so "utterly different to the other TVT's that it probably shouldn't be called a TVT."[74] Similarly, Dr. Menachem Neuman, who flew across Europe providing training sessions for Ethicon products, informed the company that "special awareness" should be paid "to the differences between the TVT/TVTO and the TVTS . . . if high cure rates and low complication rates are desired." [75] (Dr. Neuman provided a number of suggestions regarding TVT-S techniques, none of which were used in an amended IFU.)

The primary problems with the TVT-S, as compared to the predecessor devices, are the insertion tools and techniques. Throughout the TVT-S's time on the market, Ethicon was aware of complaints relating to difficulty removing the insertion device.[76] For example, in a 2006 email to David Robinson and Dan Smith, among others, Ethicon's Director of Risk Management Mark Yale described the "potential high rate of occurrence with injuries related to [the TVT-S] not coming off inserter during removal of the inserter, therefore the device is either moved from rest

[72] Robinson deposition 7-13, p116.
[73] ETH.MESH.17666960; ETH.MESH.02340577
[74] ETH.MESH.00327062.
[75] ETH.MESH.02320486
[76] ETH.MESH.02105223; ETH.MESH.03752501

position or completely pulled out along with inserter."[77] A Quality Board presentation likewise noted complaints regarding the inserter clinging to the device.[78]

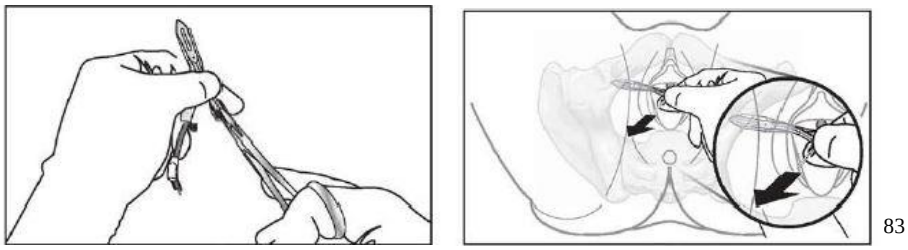
The various problems and potential explanations were summed up in a study by Hota:

> The lower overall success of TVT-S could be attributed to the difficulty that was sometimes encountered in the detachment of the introducer from the sling. During the introducer removal process, the original tensioning may have been compromised, as the introducer was moved back and forth in an attempt to release the sling from the introducer….
>
> Another point to consider is that the ends of the TVT-S are intended to be embedded within the obturator internus muscle, as opposed to passing through the obturator membrane as with the TVT-O sling. The TVT-S may theoretically migrate with time, detaching from the obturator internus muscle, whereas with TVT-O, the mesh passes through the obturator membrane as well as the obturator internus and externus muscles and the adductor magnus muscle and therefore may not be dislodged as easily. In other words, the latter approach may create a more reliable anchor for the mesh. In addition, excessive hydrodissection or sharp dissection of the periurethral space may affect the degree of attachment of the absorbable "fleece" on either end of the TVT-S. In addition, the attachment of the fleece could be compromised if a hematoma developed within the obturator internus muscle as a result of the surgical procedure.[79]

The "fleece" material is identified by Ethicon as a combination of polyglactin 910 and poly-p-dioxanone.[80] It was not used in either the TVT or TVT-O, and to my knowledge Ethicon did not perform any studies regarding its use in the pelvic floor. The TVT-S should not have launched without clinical findings showing that the new absorbable materials did not hamper insertion or integration of the device.

[77] ETH.MESH.0329316
[78] ETH.MESH.06051286
[79] Hota, Lekha S., MD, et al. TVT-Secur (Hammock) Versus TVT-Obturator: A Randomized Trial of Suburethral Sling Operative Procedures. Female Pelvic Med Reconstr. Surg. 2012, Jan-Feb;18(1):41-45.
[80] ETH.MESH.02340577

Another issue with the TVT-S insertion tools are the razor-sharp edges on the steel inserters. The Hota study found "an increased incidence of mesh exposure in the TVT-S group," and theorized that "the sharper edges of the TVT-S introducer potentially create more trauma to the vaginal epithelium and may result in high erosion rates." A "high-quality review . . . conducted to pool relevant data from randomised controlled trials" is consistent with these findings.[81] The report found that the TVT-S resulted in both more frequent vaginal exposure of mesh and mesh extrusion into the bladder or urethra, as compared to TVT-O-like devices. The TVT-S procedure also made women lose more blood than the TVT-O procedure—a statistically significant amount. Consistent with other studies, the report determined that failure rates among single-incision slings were also higher than with the transobturator approach.[82] The study concluded that "TVT-Secur is inferior to TVT and has already been withdrawn from clinical use." Once again, Ethicon did not study the potential effects of its razor-sharp instruments. The TVT-S never should have been released with this component; whatever benefits of this razor-sharp tool were clearly outweighed by the risks. It is my opinion that the sharp edges of the inserter are more likely to cause injuries to tissue and more likely to result in mesh erosion and extrusion.

 [83]

[81] Nambiar A, Cody JD, Jeffery ST. Single-incision sling operations for urinary incontinence in women (Review). The Cochrane Library, 2014, Issue 6.
[82] Maslow K, Gupta C. Randomized clinical trial comparing TVT Secur system and transvaginal obturator tape for the surgical management of stress urinary incontinence. Int Urogynecol J (2014) 25:909–914.
[83] ETH.MESH.02340568

4. Ethicon had several preferred alternatives to the TVT-S available

In general, the best course of action is to avoid using polypropylene mesh in the pelvic floor. Traditional non-surgical repairs are often helpful, and traditional surgical repairs have similar success rates as devices like the TVT, with far fewer complications.

Even so, feasible, safer, cost-effective, alternative devices were available to Ethicon at the time the TVT-S was launched and throughout the period it was marketed. As documented in the scientific literature and in Ethicon's internal communications, the TVT and TVT-O had far better success rates than the TVT-S.[84] Further, Ethicon developed (and used in its POP kits) the lightweight, large pore Ultrapro mesh, but chose not to utilize it in any treatment for SUI.[85] Any or all of these readily available options would have resulted in a more successful device with fewer complications and better outcomes.

D. Ethicon Failed to Disclose and/or Downplayed Adverse Risks, Complications, and Product Information in its Instructions for Use ("IFU") and Patient Brochures

It is important to state from the outset that Ethicon released one set of Instructions for Use ("IFU") for the TVT-S and never updated it, even as the company received more and more complaints from users and documents show growing concerns within the company itself. From launch, Ethicon's IFU failed to disclose important safety and risk information to physicians, thereby compromising the ability for all levels of surgeons to adequately and appropriately inform their patients prior to the implantation of the TVT device.

The IFU serves as the main modality for information regarding surgery. The IFU is the one document that Ethicon knew all surgeons see prior to the implantation of a mesh device.[86] In

[84] ETH.MESH.00312179; ETH.MESH.03845446; ETH.MESH.02105223; ETH.MESH.03845446; Nambiar A, Cody JD, Jeffery ST. Single-incision sling operations for urinary incontinence in women (Review). The Cochrane Library, 2014, Issue 6.
[85] Hellhammer deposition 9-13.
[86] Isenberg deposition 11-13, p566.

addition, according to Ethicon's Medical Director Piet Hinoul, physicians should be allowed to rely on the safety information in the IFU standing alone.[87] Thus, all risks associated with a medical device must be included in the products' IFU,[88] so that doctors are not left in the dark. I regularly review and rely on IFUs in my on practice. The woefully inadequate IFU for the TVT-S lists the following information in its Adverse Risks Section:

- Punctures or lacerations or injury to vessels, nerves, bladder, urethra, or bowel may occur during instrument passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies and surgical implants, PROLENE mesh and absorbable materials may potentiate or exacerbate an existing infection.
- Over-correction, i.e., too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.
- Under-correction or incorrect placement may result in incomplete or no relief from urinary incontinence.[89]

This is a nearly word-for-word recitation of the Adverse Reactions listed in the early 2000s TVT IFUs, even though, as explained, the products are quite different.[90] By contrast, the current version of the TVT IFU, although still flawed in many ways, lists the following Adverse Reactions:

- Punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel, may occur and may require surgical repair.

[87] Hinoul deposition 1-14, p1207-1208
[88] Beath deposition 7-12, p592; Weisberg deposition 8-13, p959-960.
[89] ETH.MESH.02340589
[90] ETH.MESH.05225354

- Transitory local irritation at the wound site may occur.
- As with any implant, a foreign body response may occur. This response could result in extrusion, erosion, exposure, fistula formation and/or inflammation.
- Mesh extrusion, exposure, or erosion into the vagina or other structures or organs.
- As with all surgical procedures, there is a risk of infection. As with all foreign bodies, PROLENE Mesh may potentiate an existing infection.
- Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.
- Acute and/or chronic pain
- Voiding dysfunction
- Pain with intercourse which in some patients may not resolve.
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur.
- Recurrence of incontinence
- Bleeding including hemorrhage, or hematoma.
- One or more revision surgeries may be necessary to treat these adverse reactions.
- PROLENE Mesh is a permanent implant that integrates into the tissue. In cases in which the PROLENE Mesh needs to be removed in part or whole, significant dissection may be required.

OTHER ADVERSE REACTIONS

- Seroma
- Urge incontinence
- Urinary frequency

- Urinary retention
- Adhesion formation
- Atypical vaginal discharge
- Exposed mesh may cause pain or discomfort to the patient's partner during intercourse.
- Death.[91]

As explained throughout this report and described in more detail below, the IFU for the TVT-S fails to disclose numerous adverse risks, safety information, and warnings that were well-known to Ethicon while the TVT-S was being marketed. Most strikingly, the IFU fails to mention pelvic pain or dyspareunia, which are extremely common complications of mesh implantation. More specifically, the TVT-S IFU fails to warn doctors of the known risks of, among other things: death, acute and chronic pelvic pain, acute and chronic vaginal pain, permanent dyspareunia, injury and pain to partner during sexual intercourse, sexual dysfunction, chronic infections, abscess formation, permanent nerve damage, defecatory dysfunction, chronic foreign body reaction, lifelong risk of erosion and extrusion, severe vaginal scarring, inability to remove the device, the need for multiple surgical interventions that carry with them significant risks of morbidity, the development of worsening incontinence and urinary dysfunction, including urinary urgency, urinary urge incontinence, and urinary retention. The IFU also fails to mention, among other things, the research showing that polypropylene is carcinogenic and that Prolene is cytotoxic. And the IFU omits any mention of the fact that Prolene mesh is known to degrade, contract, and shrink.

As described throughout this report, my review of internal documents and the depositions of Ethicon employees reveals that Ethicon was aware of each these risks before or at the time the

[91] TVT IFU (01/2015), available at http://hostedvl106.quosavl.com/qb/doc/0nnlfm86hbpkf33bt7pl38flvg

TVT-S was first marketed and sold.[92] In my opinion, Ethicon's failure to warn of these significant risks resulted in injuries to many women.

Ethicon also failed to include warnings in its IFU related to the increased risk of mesh extrusion in women with prior vaginal surgeries, vaginal atrophy, vaginal injury, and post-operative infection.[93] In addition, Ethicon failed to inform physicians that the TVT-S procedure performed under general anesthesia increases the risk of urinary retention, erosions, and failure of the surgery. Ethicon also failed to mention the risks associated with its new razor-sharp insertor and increased risk of certain complications relating to laser cut mesh. Finally, Ethicon did not tell physicians that the TVT-S device would not work as well in smokers or obese patients.[94] All of these risks should have been disclosed to every surgeon via the original TVT-S IFU. It is inexcusable that no amendment was made to the IFU throughout the TVT-S's marketing period.

In addition to omitting information, Ethicon also downplays and misrepresents significant information in its IFU related to certain mesh properties. For example, despite the significant amount of data regarding mesh-related inflammatory response, the IFU for TVT-S states, "Transitory local irritation at the wound site and a transitory foreign body response may occur." According to the scientific literature, my own clinical experience, deposition testimony of Ethicon employees, and Ethicon's internal documents, the foreign body response is far from "transitory."[95] As Ethicon's Associate Medical Director of Worldwide Customer Quality explained, "[F]rom what I see each day, these patient experiences are not 'transitory' at all."[96]

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[92] Hinoul deposition 6-13, p552; Beath deposition 7-13, p608; Robinson deposition 7-13, p251; ETH.MESH.00312180; ETH.MESH.04081189; ETH.MESH.02089392; ETH.MESH.04099233; ETH.MESH.03910175

[93] Isenberg deposition 11-13, p582-583, ETH.MESH.00159634; ETH.MESH.00203456

[94] ETH.MESH.00640394, Kirkemo deposition 1-14, p556-558.

[95] Robinson deposition 9-13, p1087-1089; Hinoul deposition, 1-14, p1192-1199.

[96] ETH.MESH.04093125

Notably, the word "transient" no longer modifies "foreign body response" in the latest TVT IFU. Further, Ethicon states in its IFU that the polypropylene mesh is not subject to degradation, which is inconsistent with Ethicon's own internal findings, as described in detail above.

In short, Ethicon not only failed to disclose certain risks associated with the product, it downplayed or inaccurately portrayed known issues related to mesh implantation. Thus, Ethicon prevented physicians from having an appropriate and accurate informed consent discussion with their patients by concealing and misrepresenting this type of information. The information Ethicon provided in patient brochures was no better, similarly downplaying risks, omitting safety information, and improperly equating the TVT-S with the TVT, as though the risks and benefits were the same.[97] As a result, numerous patients have suffered injuries from the TVT-S device that might have been avoided.

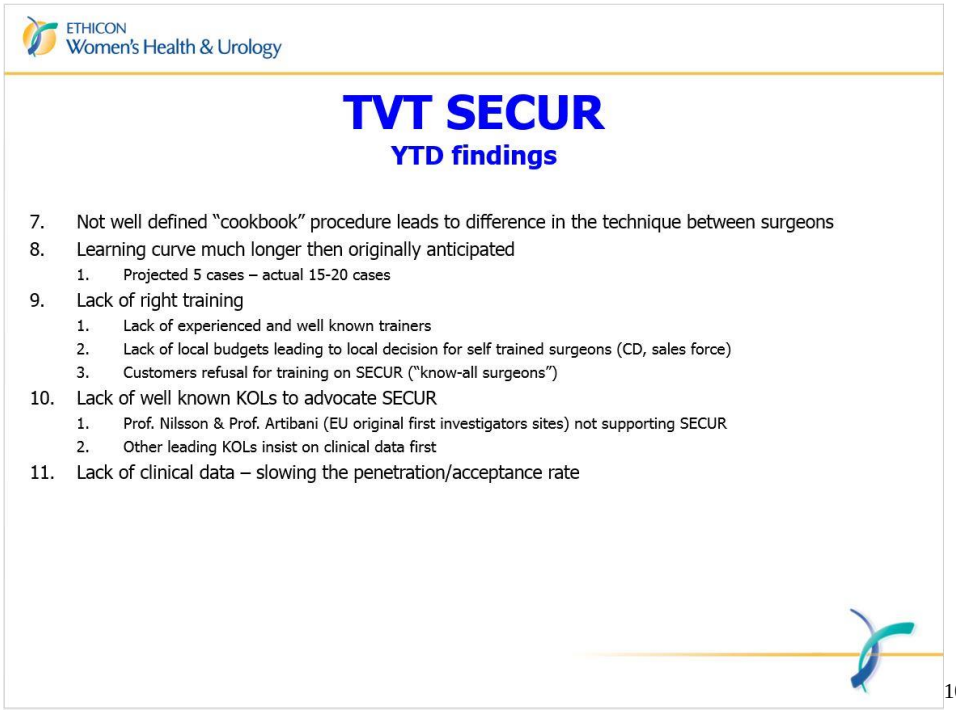
E. Ethicon Failed to Provide Adequate Training for Surgeons Using the TVT-S

As explained above, the implantation of the TVT-S device was a very different experience for surgeons compared to the TVT and TVT-O. Unfortunately, Ethicon left them in the dark.

For example, in addition to the tension and inserter issues described in this report, Ethicon did not provide surgeons with accurate information regarding the incision size for implantation. The IFU states that the incision size should be 1.0-1.5 cm.[98] But Dr. Arnaud's "cookbook"[99] and "procedural pearls"[100] suggested a larger incision size, in order to reduce the risk of erosion or exposure.[101] The new size was larger than what was required with older slings.[102]

[97] ETH.MESH.08003263; ETH.MESH.08003279
[98] ETH.MESH.02340568
[99] ETH.MESH.03752501; ETH.MESH.00519476
[100] ETH.MESH.07039973
[101] ETH.MESH.17666960
[102] ETH.MESH.17666960

According to their own documents, Ethicon employees were well-aware that surgeons were struggling.[103]



[104]

Even Ethicon KOLs needed dozens of surgeries before they became something close to proficient in utilizing the TVT-S.[105]

It is my opinion to a reasonable degree of medical certainty that Ethicon should not have launched the TVT-S without better instructions, and should have provided better training to all surgeons. This issue might have been avoided with extensive pre-launch clinical studies, but none were performed.[106] Internal Ethicon documents suggest that the company continued to

[103] ETH.MESH.0324086; ETH.MESH.0329557; ETH.MESH.00330141; ETH.MESH.03922618; ETH.MESH.00874445; ETH.MESH.00642325; ETH.MESH.02105223; ETH.MESH.03845446; ETH.MESH.01784428; ETH.MESH.03752501
[104] ETH.MESH.02105223
[105] ETH.MESH.02105223; ETH.MESH.03845446; ETH.MESH.04048515
[106] ETH.MESH.00134795

market the product as something that could be easily implanted, for fear of losing market share.[107]

V. Conclusion

In sum, I concur with the results of Ethicon's (unpublished) summary of first-year data on the TVT-S, which showed that nearly a third of women experienced "major" complications: "As long as complications occur at the rate seen in this study . . . the single-incision procedure cannot be recommended as a first line treatment for [SUI]."[108] As explained throughout this report, the TVT-S is a defective device sold with faulty instructions, which never should have been brought to market. As a result of the TVT-S, many women have experienced severe complications that are in many cases irreversible.

Date: January 25, 2016

DANIEL ELLIOTT, M.D.

[107] ETH.MESH.00858636
[108] ETH.MESH.02916611

EXHIBIT A

Curriculum Vitae and Bibliography
Daniel S Elliott, MD

Present Academic Rank and Position

Consultant - Department of Urology, Mayo Clinic, Rochester, Minnesota	07/2003 - Present
Associate Professor of Urology - Mayo Clinic College of Medicine	01/2013 - Present

Education

Biola University - BS, Biological Science	1988
School of Medicine, Loma Linda University - MD	1993
Mayo School of Graduate Medical Education, Mayo Clinic College of Medicine - Internship, General Surgery	1993 - 1994
Mayo School of Graduate Medical Education, Mayo Clinic College of Medicine - Resident, Urologic Surgery	1994 - 1999
Baylor College of Medicine - Fellow, Neurourology, Urodynamics and Voiding Dysfunction	1999 - 2000

Certification

Board Certifications

American Board of Urology

Urology	2002 - 2012
Urology/Female Pelvic Medicine and Reconstructive Surgery	2013 - Present

Honors and Awards

AUA Resident Award - John D. Silbar North Central Section	10/1998
Urology Grant Recipient - Pfizer Scholars	01/1999
DeWeerd Travel Award Recipient - Awarding Organization	06/1999
Annual Audio-Visual Award - AUA - American Urological Association, Washington, District of Columbia	05/2011
Best Reviewer in 2011 Award - Urodynamics/Incontinence/Female Urology/Neurourology - The Journal of Urology	05/2012
Annual Audio-Visual Award - AUA - American Urological Association, San Diego, California	05/2013
Best Reviewer in 2012 Award - Urodynamics/Incontinence/Female Urology/Neurourology - The Journal of Urology	05/2013
Kelalis Resident Essay Competition - Minnesota Urological Society, Lakeland, Minnesota	02/2015
The North Central Traveling Fellowship Award - North Central Section American Urological Association	11/2015

Previous Professional Positions and Major Appointments

Senior Associate Consultant - Department of Urology, Mayo Clinic, Rochester, Minnesota	07/2000 - 06/2003
Assistant Professor of Urology - Mayo Clinic College of Medicine	04/2002 - 12/2012

Professional and Community Memberships, Societies, and Services

Professional Memberships and Services

American Association of Clinical Urologists	
Member	1998 - 2005
American Medical Association	
Member	1991 - 2001
American Urological Association	
Member	2000 - Present
European Association of Urology	
International Member	03/2013 - Present
Section of Female and Functional Urology	
International Member	04/2013 - Present
Section of Genitourinary Reconstructive Surgeons	
International Member	03/2013 - Present
Committee Member	04/2014 - Present
International Continence Society	
Member	2001 - Present
International Pelvic Pain Society	
Member	05/2014 - Present
International Urogynecologic Association	
Member	05/2013 - Present
International Urogynecologic Society	
Member	2003 - Present
Minimally Invasive Robotic Association	
Member	2005 - Present
Minnesota Medical Association	
Member	2002 - Present
Zumbro Valley Medical Society	
Member	2002 - Present
Minnesota Urological Society	
Member	2006 - Present
Olmsted County Medical Association	
Member	2002 - Present
Society for Urodynamics & Female Urology	
Member	2002 - Present
Education Committee	
Committee Member	08/2014 - Present
Society of Laparoendoscopic Surgeons	
Member	2005 - Present
Society of Urologic Prosthetic Surgeons	
Member	2005 - Present

Journal Responsibilities

Journal Editorial Responsibilities

Journal of Gynecology and Obstetrics	
Editorial Board Member	

Journal of Robotic Surgery
Consulting Editor

Journal Other Responsibilities

Archives of Gynecology and Obstetrics
Reviewer
Canadian Urological Association Journal
Reviewer
Cleveland Clinic Journal of Medicine
Reviewer
Contemporary Clinical Trials
Reviewer
European Journal of Obstetrics & Gynecology and Reproductive Biology
Reviewer
European Urology
Reviewer
International Urogynecology Journal
Reviewer
Journal of Endourology
Reviewer
Journal of Investigative Urology
Reviewer
Mayo Clinic Health Letter
Reviewer
Mayo Clinic Proceedings
Reviewer
Nature Clinical Practice Urology
Reviewer
Neurourology and Urodynamics
Reviewer
Obstetrics & Gynecology International Journal
Reviewer
The Journal of Urology
Reviewer
Urologia Internationalis
Reviewer

Educational Activities

Teaching Intramural

Prostate Pathology 03/2005
Mayo Medical School
Rochester, Minnesota

Institutional/Departmental Administrative Responsibilities, Committee Memberships, and Other Activities

Mayo Clinic

Mayo Clinic Formulary Committee
- Committee Member — 2000 - 2003

Mayo Clinic in Rochester

Department of Urology
- Clinical Competency Committee
  - Chair — 01/01/2015 - Present
  - Committee Member — 10/15/2013 - Present
- Clinical Practice Committee
  - Committee Member — 2000 - 2004
- Education Committee
  - Committee Member — 02/11/2003 - 11/11/2008
  - Committee Member — 10/15/2013 - Present

Presentations Extramural

National or International

Invited

Robotic Urogynecologic Surgery — 03/2008
3rd Annual World Robotic Urology Symposium
Orlando, Florida

Robotic Sacrocolpopexy — 01/2009
2009 International Robotic Urology Symposium (IRUS), Henry Ford Health System
Las Vegas, Nevada

Current Status Robotic GYN Surgery — 01/2010
2010 International Robotic Urology Symposium (IRUS), Henry Ford Health System
Las Vegas, Nevada

Robotic Sacrocolpopexy — 09/2010
28th World Congress on Endourology and SWL
Chicago, Illinois

Female Urology — 09/2010
28th World Congress on Endourology and SWL
Chicago, Illinois

Optimizing Quality of Life With Regard to Urologic Function After Sacrectomy — 01/2013
The 4th Annual Sacral Tumor Study Group Conference, Massachusetts General Hospital
Boston, Massachusetts

A Comparison of Artificial Urinary Sphincter Device Outcomes Among Patients With and Without Diabetes — 02/2015
Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)

Scottsdale, Arizona

A Prospective Evaluation of Complications After Artificial Urinary Sphincter Placement and Their Impact on Device Survival — 02/2015
Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)
Scottsdale, Arizona

Autologous Transobturator Urethral Sling Placement for Female Stress Urinary Incontinence — 02/2015
Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)
Scottsdale, Arizona

Effects of Radiation Therapy on Device Survival Among Individuals with Artificial Urinary Sphincters — 02/2015
Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)
Scottsdale, Arizona

Holmium Laser Excision of Genitourinary Mesh Exposure Following Anti-Incontinence Surgery: Minimum 6 Month Follow-up — 02/2015
Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)
Scottsdale, Arizona

Outcomes for Artificial Urinary Sphincter Placement After Prior Male Urethral Sling Failure — 02/2015
Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)
Scottsdale, Arizona

The Effect of BMI on Primary Artificial Urinary Sphincter Outcomes Among Males with Stress Urinary Incontinence — 02/2015
Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)
Scottsdale, Arizona

Treatment of Bladder and Urethral Mesh Erosion: Remove and Reconstruct — 02/2015
Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)
Scottsdale, Arizona

Urethral Management During Artificial Urinary Sphincter Explantation for Erosion — 02/2015
Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)
Scottsdale, Arizona

Male Urinary Incontinence Management — 05/2015
Association Française d’Urologie (AFU) / American Urological Association (AUA)
New Orleans, Louisiana

Negative Impact of Prior Sling on AUS Device Survival 11/2015
North Central Section of the American Urological Association (AUA)
United States of America

Oral

Long Term Follow-Up of Endoscopically Treated Upper Tract Transitional Cell Carcinoma 04/1995
American Urological Association Annual Meeting
Las Vegas, Nevada

Long Term Analysis of 323 AMS 800 Artificial Urinary Sphincters 05/1996
Urodynamics Subsection Meeting, American Urological Association
Orlando, Florida

Transabdominal Enzymatic Ablation of the Prostate in the Canine Model: Evaluation for Use for the Treatment of Outflow Obstruction Due to Benign Prostatic Hyperplasia 05/1996
Urodynamics Subsection Meeting, American Urological Association
Orlando, Florida

Analysis of Functional Durability of AMS 800 Artificial Urinary Sphincter: The Mayo Clinic Results 04/1997
American Urological Association Annual Meeting
New Orleans, Louisiana

Long Term Follow-Up Primary Realignment of Urethral Disruption Following Pelvic Fracture 04/1997
American Urological Association Annual Meeting
New Orleans, Louisiana

Does Reoperation on an Artificial Urinary Sphincter Increase the Likelihood for Further Reoperations for Mechanical or Nonmechanical Failure? 06/1998
American Urological Association Annual Meeting
San Diego, California

Is Nephroureterectomy Necessary in All Cases of Upper Tract Transitional Cell Carcinoma? Long Term Results of Conservative Endourology Management of Upper Tract Transitional Cell Carcinoma in Individuals with Normal Contralateral Kidneys 05/1999
American Urological Association Annual Meeting
Dallas, Texas

Durability of Cadaveric Pubovaginal Sling 06/2001
American Urological Association Annual Meeting
Anaheim, California

Does the Addition of Antibiotic Prophylaxis to CIC Alter the Incidence of UTI? 06/2002
American Urological Association Annual Meeting

Orlando, Florida

Surgical Approach for Placement of SPARC Suburethral Sling — 10/2002
North Central Section, American Urological Association
Chicago, Illinois

SPARC suburethral sling: technique and results (Video Presentation) — 11/2002
Western Section, American Urological Association
Kauai, Hawaii

Robotic laparoscopic sacrocolpopexy: new surgical technique for the treatment of vaginal vault prolapse (Video Presentation) — 04/2003
American Urological Association
Chicago, Illinois

08/2004
Colloquium-ICS/IUGA 2004
Paris, France

Robotic-Assisted Laparoscopic Management of Vaginal Vault Prolapse — 12/2005
Minimally Invasive Robotics Association
Innsbruck, Austria

Advancement in Salvage Procedure Following Failed Artificial Urinary Sphincter: Tandem Transcorporal Artificial Urinary Sphincter Cuff Technique (Video Presentation) — 05/2006
American Urological Association
Atlanta, Georgia

Tandem Transcorporal Artificial Urinary Sphincter Cuff Salvage Technique Following Previous Cuff Erosion and Infection: Surgical Description and Outcome — 10/2006
Western Section, American Urological Association
Maui, Hawaii

Assessment of Durability of Robotic Sacrocolpopexy for the Treatment of Vaginal Vault Prolapse — 01/2007
Minimally Invasive Robotics Association
New York, New York

Minimally Invasive Advances: Stress Incontinence — 02/2007
Mayo Clinic Rochester, Department of Urology
Kohala Coast, Hawaii

Treatment Options for the Failed Sling — 02/2007
Mayo Clinic Rochester, Department of Urology
Kohala Coast, Hawaii

05/2007
American Urological Association Annual Meeting

Anaheim, California

Robotics use in Gynecology: the Mayo Clinic experience 06/2007
Robotic Surgery: Facts or Fiction?
Milano, Italy

Indication and Management of Artificial Urinary Sphincter 10/2007
7th Osijek Urological Days
Osijek, Croatia

Robotics Use in Gyenocology 10/2007
7th Osijek Urological Days
Osijek, Croatia

Robotic Urogynecologic Surgery 03/2008
3rd Annual World Robotic Urlogy Symposium
Orlando, Florida

Latest Advances and Treatment of Complications in Minimally Invasive Treatments for Stress Incontinence 05/2008
American Urological Association (AUA)
Orlando, Florida

Severe, recurrent bladder neck contracture after prostatectomy: Salvage with urethral wall stent(Video and Poster Presentation) 05/2008
American Urological Association (AUA)
Orlando, Florida

Surgical Advances of Stress Urinary Incontinence 05/2008
Indian American Urological Association (IAUA)
Orlando, Florida

Robotic Sacrocolpopexy 01/2009
International Robotic Urology Symposium, Henry Ford Health System
Las Vegas, Nevada

Management of Complications Following Anti-Incontinence Procedures 02/2009
Mayo Clinic, Department of Urology, Rochester Meeting
Kona, Hawaii

Minimally Invasive Advances: Stress Incontinence 02/2009
Mayo Clinic, Department of Urology, Rochester Meeting
Kona, Hawaii

Overactive Bladder: Current Concepts of Management 02/2009
Mayo Clinic, Department of Urology, Rochester Meeting
Kona, Hawaii

04/2009
American Urological Association (AUA)
Chicago, Illinois

Robotic repair for vaginal prolapse has significant benefits 11/2009
North Central Section of the AUA - 83rd Annual Meeting
Scottsdale, Arizona

Current Status Robotic GYN Surgery 01/2010
International Robotic Urology Symposium, Henry Ford Health System
Las Vegas, Nevada

Robotics for Female Pelvic Reconstruction: Who, When and What? 05/2010
American Urological Association (AUA)
San Francisco, California

Results of Urethral Wrap As Salvage Treatment Option Following Multiple Failed Artificial Urinary Sphincters 09/2010
North Central Section of the AUA
Chicago, Illinois

Small intestinal submucosa urethral wrap as a salvage treatment option following multiple failed artificial urinary sphincters 05/2011
Audio-Visual
American Urological Association (AUA)
Washington, District of Columbia

Long-Term Results of Small Intestinal Submucosa at Artificial Urinary Sphincter Placement for Management of Persistent / Recurrent Incontinence Following Multiple Sphincter Failures and Erosions 10/2011
North Central Section of the AUA
Rancho Mirage, California

OAB Current Concepts and Management 02/2012
Mayo Clinic Reviews in Urology
Kohala Coast, Hawaii

Transvaginal Mesh Kits Complications and Alternatives 02/2012
Mayo Clinic Reviews in Urology
Kohala Coast, Hawaii

Treatment and Evaluation of the Complicated Artificial Urinary Sphincter Patient 02/2012
Mayo Clinic Reviews in Urology
Kohala Coast, Hawaii

Vaginal Mesh for POP: what's the data show? 05/2012
American Urological Association (AUA)
Atlanta, Georgia

How do different centres perform Robot-assisted-Sacrocolpopexy? 4th Annual Society of European Robotic Gynecological Surgery (SERGS) Marseille, France	06/2012
Comparative Surgical Complications of the Robotic Sacrocolpopexy for Pelvic Organ Prolapse vs. Traditional Transabdominal Sacrocolpopexy European Robotic Urology Symposium (ERUS) London, United Kingdom	09/2012
Infection of Antibiotic-Coated Artificial Urinary Sphincters North Central Section of the AUA Chicago, Illinois	10/2012
Effect of prior radiotherapy and ablative therapy on surgical outcomes for the treatment of rectourethral fistulas Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Las Vegas, Nevada	02/2013
Impact of Patient Obesity on Robotic Sacrocolpopexy for the Treatment of Vaginal Vault Prolapse Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Las Vegas, Nevada	02/2013
Robotic Transvesical Rectourethral Fistula Repair Following a Robotic Radical Prostatectomy (Video Presentation) Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Las Vegas, Nevada	02/2013
The Impact of Prior Radiotherapy on Outcomes Following Surgical Repair of a Rectourethral Fistula in Men with Prostate Cancer Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Las Vegas, Nevada	02/2013
Effect of prior radiotherapy and ablative therapy on surgical outcomes for the treatment of rectourethral fistulas American Urological Association (AUA) San Diego, California	05/2013
Impact of Patient Obesity on Robotic Sacrocolpopexy for the Treatment of Vaginal Vault Prolapse American Urological Association (AUA) San Diego, California	05/2013
Long Term Risk for Repeat Anti-Incontinence Surgery following Urethrolysis: A Review of 100 Patients American Urological Association (AUA) San Diego, California	05/2013

Long-Term Outcomes of Patients Undergoing the Standard Versus Modified (5 Points of Fixation, 1 Point of Plication) Technique for Virtue Male Sling Placement (Video Presentation) American Urological Association (AUA) San Diego, California	05/2013
Robotic Transvesical Rectourethral Fistula Repair Following a Robotic Radical Prostatectomy (Video Presentation) American Urological Association (AUA) San Diego, California	05/2013
The Impact of InhibiZone on Artificial Urinary Sphincter Infection Rate American Urological Association (AUA) San Diego, California	05/2013
Impact of patient obesity on robotic sacrocolpopexy for the treatment of vaginal vault prolapse 3rd International Meeting "Challenges in Endourology & Functional Urology" Paris, France	06/2013
Long-Term Outcomes for Artificial Urinary Sphincter Reimplantation Following Prior Device Explantation for Erosion and/or Infection South Central Section of the AUA Chicago, Illinois	09/2013
Effect of prior radiotherapy and ablative therapy on surgical outcomes for the treatment of rectourethral fistulas 2nd Joint Section Meeting of ESFFU, ESGURS, and ESOU Tübingen, Germany	10/2013
Impact of patient obesity on robotic sacrocolpopexy for the treatment of vaginal vault prolapse 2nd Joint Section Meeting of ESFFU, ESGURS, and ESOU Tübingen, Germany	10/2013
Long Term Risk for Need to Repeat Anti-Incontinence Surgery Following Urethrolysis: A Review of 144 Patients North Central Section of the AUA Naples, Florida	10/2013
Long-term impact of artificial urinary sphincter reimplantation following prior device explantation for erosion and/or infection 2nd Joint Section Meeting of ESFFU, ESGURS, and ESOU Tübingen, Germany	10/2013
Long-Term Outcomes for Artificial Urinary Sphincter Reimplantation after Explanation for Erosion or Infection North Central Section of the AUA Naples, Florida	10/2013

Simultaneous Cuff-Only Artificial Urinary Sphincter at Augmentation Cystoplasty in Children and Young Adults North Central Section of the AUA Naples, Florida	10/2013
Long-Term Device Outcomes for Artificial Urinary Sphincter Reimplantation Following Prior Explantation for Erosion or Infection Society of Urodynamics Female Pelvic Medicine & Urogenital Reconstruction Miami, Florida	02/2014
Risk Factors for Intraoperative Conversion During Robotic Sacrocolpopexy Society of Urodynamics Female Pelvic Medicine & Urogenital Reconstruction Miami, Florida	02/2014
Results of artificial urinary sphincter reimplantation following previous erosion and/or infection 29th Annual Congress of the European Association of Urology Stockholm, Sweden	04/2014
Autologous Transobturator Mid-Urethral Sling Placement: A Novel Outpatient Procedure for Female Stress Urinary Incontinence (Video Presentation) American Urological Association (AUA) Orlando, Florida	05/2014
Surgical Management of Female Benign Urethral Stricture Disease: A Ten Year Experience American Urological Association (AUA) Orlando, Florida	05/2014
Autologous Transobturator Mid-Urethral Sling Placement for Female Stress Urinary Incontinence (Video Presentation) North Central Section of the American Urological Association (AUA) Chicago, Illinois	09/2014
Urethral Management at the Time of Artificial Urinary Sphincter Erosion, Is Urethral Catheterization Alone Enough? North Central Section of the American Urological Association (AUA) Chicago, Illinois	09/2014
Holmium Laser Excision of Genitourinary Mesh Exposure Following Anti-Incontinence Surgery: Minimum 6 Month Follow-up American Urological Association (AUA) New Orleans, Louisiana	05/2015
A Comparison of Artificial Urinary Sphincter Device Outcomes Among Patients with and Without Diabetes North Central Section of the American Urological Association (AUA) Amelia Island, Florida	11/2015

Autologous Transobturator Urethral Sling Placement for Female Stress Urinary Incontinence — 11/2015
North Central Section of the American Urological Association (AUA)
Amelia Island, Florida

Effects of Radiation Therapy on Device Survival Among Individuals with Artificial Urinary Sphincters — 11/2015
North Central Section of the American Urological Association (AUA)
Amelia Island, Florida

Infection/Erosion Rates for Artificial Urinary Sphincter Revision After Mechanical Device Failure or Urethral Atrophy — 11/2015
North Central Section of the American Urological Association (AUA)
Amelia Island, Florida

Long Term Continence Outcomes and Retreatment Rates Following Artificial Urinary Sphincter Placement: An Analysis of 1082 Cases at Mayo Clinic — 11/2015
North Central Section of the American Urological Association (AUA)
Amelia Island, Florida

The Prospective Impact of Body Mass Index on Primary Artificial Urinary Sphincter Outcomes Among Males with Stress Urinary Incontinence — 11/2015
North Central Section of the American Urological Association (AUA)
Amelia Island, Florida

Poster

Robot-Assisted Laparoscopic Sacrocolpopexy for Treatment of High Grade Vaginal Vault Prolapse: Surgical Technique and Initial Experience — 09/2007
29th Congress of the Societe Internationale d'Urologie
Paris, France

Robot Sacrocolpopexy: A Review of the Learning Curve in Fifty Casesl — 01/2011
4th World Congress on Controversies in Urology (CURy)
Paris, France

Impact of Radiotherapy on Surgical Repair and Outcomes in Patients with Rectourethral Fistula. — 06/2012
67th Annual Meeting of the Canadian Urological Association
Alberta, Canada

Outcomes and Predictors of Reoperation After Sling Release Surgery — 05/2014
American Urological Association (AUA)
Orlando, Florida

Term Device Outcomes for Artificial Urinary Sphincter Reimplantation Following Prior Explantation for Erosion or Infection — 05/2014
American Urological Association (AUA)
Orlando, Florida

Factors Associated with Intraoperative Conversion During Robotic Sacrocolpopexy 09/2014
North Central Section of the American Urological Association (AUA)
Chicago, Illinois

A Prospective Evaluation of Complications After Artificial Urinary Sphincter Placement and Their Impact on Device Survival 05/2015
American Urological Association (AUA)
New Orleans, Louisiana

Artificial Urinary Sphincter Outcomes in Octogenarians 05/2015
American Urological Association (AUA)
New Orleans, Louisiana

Effects of Radiation Therapy on Device Survival Among Individuals with Artificial Urinary Sphincters 05/2015
American Urological Association (AUA)
New Orleans, Louisiana

Perioperative Impact of Androgen Deprivation Therapy on Artificial Urinary Sphincter Placement 10/2015
Western Section of the AUA
Indian Wells, California

The Protective Impact of Body Mass Index on Primary Artificial Urinary Sphincter Outcomes Among Males with Stress Urinary Incontinence 10/2015
South Central Section of the American Urological Association (AUA)
Scottsdale, Arizona

Regional

Invited

Rectocele 10/2004
Office of Women's Health brown bag
Rochester, Minnesota

Incontinence and Other Urological Issues 08/2007
Radio Broadcast, Hosted by Dr. Thomas Shives
HealthLine - KROC Radio
Rochester, Minnesota

A Practical Approach to Treating Incontinence 10/2008
Clinical Reviews, Rochester Civic Center
Rochester, Minnesota

A Practical Approach to Treating Incontinence 11/2008
Clinical Reviews, Rochester Civic Center
Rochester, Minnesota

Incontinence and Other Urological Issues 03/2010
Radio Broadcast, Hosted by Dr. Thomas Shives
Medical Edge Weekend - KROC Radio
Rochester, Minnesota

Urinary Incontinence 03/2011
Radio Broadcast, Hosted by Dr. Thomas Shives
Medical Edge Weekend - KROC Radio
Rochester, Minnesota

Incontinence: Causes and Treatments 02/2013
Prostate Cancer Support Group
Rochester, Minnesota

Urinary Incontinence 05/2014
Radio Broadcast, Hosted by Dr. Thomas Shives
Medical Edge Weekend - KROC Radio
Rochester, Minnesota

Autologous Transobturator Urethral Sling Placement for Female Stress Urinary Incontinence 03/2015
Minnesota Urological Society (MUS) Spring Seminar
Minneapolis, Minnesota

Management of Concomitant SUI and Stricture Disease 08/2015
2015 Mayo Clinic Updates in Urology and Case Conference Program Schedule
Rochester, Minnesota

Managing the Mesh Mess - Diagnosing and Managing Mesh Complications and Non-Mesh Alternatives 08/2015
2015 Mayo Clinic Updates in Urology and Case Conference Program Schedule
Rochester, Minnesota

Surgical Tips to Optimize Outcomes of AUS Placement 08/2015
2015 Mayo Clinic Updates in Urology and Case Conference Program Schedule
Rochester, Minnesota

Incontinence 12/2015
Radio Broadcast, Hosted by Tracy McCray
Mayo Clinic Radio
Rochester, Minnesota

Oral

Paratesticular Angiomyofibroblastoma 09/1995
North Central Section, American Urological Association
Minneapolis, Minnesota

Does the Degree of Preoperative Elevation PSA Exclude a Patient for 10/1996

Consideration for Radical Retropubic Prostatectomy?
North Central Section, American Urological Association
Tucson, Arizona

Does Reoperation of an Artificial Sphincter Place the Patient at an Increased Risk for Subsequent Reoperation — 10/1998
North Central Section, American Urological Association
Amelia Island, Florida

Combined Stent and Artificial Urinary Sphincter for Management of Severe Recurrent Bladder Neck Contractures and Stress Incontinence after Prostatectomy: A Long-Term Evaluation. — 10/2000
North Central Section, American Urological Association
Phoenix, Arizona

Does Nocturnal Deactivation of the Artificial Urinary Sphincter Lessen the Risk for Urethral Atrophy? — 10/2000
North Central Section, American Urological Association
Phoenix, Arizona

Is Fascia Lata Allograft Material Trustworthy for Pubovaginal Sling Repair — 10/2000
North Central Section, American Urological Association
Phoenix, Arizona

Robotics Surgery for Vaginal Prolapse — 06/2007
Controversies in Women's Health Symposium 2007
Nisswa, Minnesota

Unclassified

Artificial Urinay Sphincter Mechanical Failures: Is It Better To Replace The Entire Device Or Just The Malfunctioning Component? — 02/2016
Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)

Effects Of Smoking Status On Device Survical Among Individuals Undergoing Artificial Urinary Sphincter Placement — 02/2016
Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)

Long-Term Outcomes Following Artificial Urinary Sphincter Placement: An Analysis Of 1082 Cases At Mayo Clinic — 02/2016
Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)

Long-Term Subjective And Functional Outomes Of Primary And Secondary Artificial Urinary Sphincter Implantations Among Men With Stress Urinary Incontinence — 02/2016
Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)

Predictors Of Poor Patient Satisfaction Following Primary AUS Placement Among Men With And Without A Prior History Of Radiation — 02/2016
Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)

Temporal Pattern Of Artificial Urinary Sphincter (AUS) Cuff Erosions Indicating Differing Etiologies Of AUS Cuff Erosions — 02/2016
Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)

Visiting Professorship

Visiting Professorships

Minnesota Urological Society Pyelogram Conference — 11/07/2014
The Artificial Urinary Sphincter: Proper Patient Selection, Implantation and Troubleshooting
Lakeland, Minnesota, United States of America

University of California Irvine — 03/16/2015
AUS: Patient Selection and Complications Management
Irvine, California, United States of America

Research Grants Awarded

Completed Grants

Federal

Co-Investigator	Selenium and Vitamin E Cancer Prevention Trial (SELECT). Funded by National Cancer Institute. (U10 CA 37429-SELECT)	01/2010 - 12/2010

Industry

Principal Investigator	Are There Histological and Tensile Strength Variations in Autologous, Allograft and SIS Pubovaginal Slings Over Time Using the Rabbit Model. Funded by Mentor Corporation. (MENTOR #5, 1A4575)	10/2002 - 09/2003
Co-Investigator	Single Looped Mechanical Urinary Sphincter: Determination of Required Urethral Constriction Forces to Provide Adequate Urinary Continence in the Canine Model. Funded by Dacomed, Inc.. (Dacomed #1)	10/1995 - 12/1995
Co-Investigator	Clinical Investigation of the Safety and Performance of Timm Medical Technologies' Artificial Urinary Sphincter (TIMM-AUS). Funded by Timm Medical Technologies. (Timm # 1)	06/1999 - 02/2005
Co-Investigator	A Randomized, Double-Blind, Parallel-Group Study to Investigate the Effects of a Single Oral Dose of L-753099 Compared to Placebo and Tolerodine on Urodynamic Parameters in Healthy Male Volunteers. Funded by Merck & Co., Inc.. (Merck 138)	07/1999 - 12/2003
Co-Investigator	The Safety, Local Tolerability, Pharmacokinetics, and Risk Benefit of Oxybutynin Transvaginal Rings (TVR) in Women with a History of Overactive Bladder. Funded by Advanced Biologics. (BIOLOGICS #1)	01/2001 - 12/2003

Co-Investigator	An Eight-Week, Double-Blind, Randomized, Parallel Group Design, Multicenter Study of FLOMAX Capsules, 0.4 mg Daily Vs. Placebo, in Female Patients w/ Lower Urinary Tract Symptoms (LUTS) w/ a Significant Component of Voiding Symptoms. Funded by Boehringer Ingelheim. (BOEHRINGER #34)	06/2001 - 07/2003
Co-Investigator	Veritas Collagen Matrix Urological Sling Postmarketing Clinical Study Protocol. Funded by Bio-Vascular, Inc.. (BIOVASCULAR #1)	10/2001 - 09/2003

Mayo Clinic

Principal Investigator	Transurethral Enzymatic Ablation of the Prostate (TEAP); Short-term Concentration Study. Funded by Department Discretionary Funds. (Immuno 2)	09/1995 - 12/2003

Bibliography

Peer-reviewed Articles

1. Gleason PE, **Elliott DS**, Zimmerman D, Smithson WA, Kramer SA. Metastatic testicular choriocarcinoma and secondary hyperthyroidism: case report and review of the literature. J Urol. 1994 Apr; 151(4):1063-4. PMID:8126794

2. **Elliott DS**, Blute ML, Patterson DE, Bergstralh EJ, Segura JW. Long-term follow-up of endoscopically treated upper urinary tract transitional cell carcinoma. Urology. 1996 Jun; 47(6):819-25. PMID:8677570 DOI:10.1016/S0090-4295(96)00043-X

3. **Elliott DS**, Barrett DM. Long-term followup and evaluation of primary realignment of posterior urethral disruptions. J Urol. 1997 Mar; 157(3):814-6. PMID:9072573

4. **Elliott DS**, Barrett DM. The artificial urinary sphincter in the female: indications for use, surgical approach and results. Int Urogynecol J Pelvic Floor Dysfunct. 1998; 9(6):409-15. PMID:9891964

5. **Elliott DS**, Barrett DM. Mayo Clinic long-term analysis of the functional durability of the AMS 800 artificial urinary sphincter: a review of 323 cases. J Urol. 1998 Apr; 159(4):1206-8. PMID:9507835

6. Brown JA, **Elliott DS**, Barrett DM. Postprostatectomy urinary incontinence: a comparison of the cost of conservative versus surgical management. Urology. 1998 May; 51(5):715-20. PMID:9610584

7. **Elliott DS**, Barrett DM. The artificial genitourinary sphincter. Digital Urology Journal. 1998 Jul.

8. **Elliott DS**, Timm GW, Barrett DM. An implantable mechanical urinary sphincter: a new nonhydraulic design concept. Urology. 1998 Dec; 52(6):1151-4. PMID:9836575

9. **Elliott DS**, Boone TB. Urethral devices for managing stress urinary incontinence. Journal of Endourology. 2000 Feb; 14(1):79-83. PMID:10735576

10. **Elliott DS**, Barrett DM. Artificial urinary sphincter implantation using a bulbous urethral cuff: perioperative care. Urol Nurs. 2000 Apr; 20(2):89-90, 95-8. PMID:11998129

11. Frank I, **Elliott DS**, Barrett DM. Success of de novo reimplantation of the artificial genitourinary sphincter. J Urol. 2000 Jun; 163(6):1702-3. PMID:10799164

12. Petrou SP, **Elliott DS**, Barrett DM. Artificial urethral sphincter for incontinence. Urology. 2000 Sep 1; 56(3):353-9. PMID:10962293

13. **Elliott DS**, Boone TB. Is fascia lata allograft material trustworthy for pubovaginal sling repair? Urology. 2000 Nov 1; 56(5):772-6. PMID:11068297

14. **Elliott DS**, Boone TB. Recent advances in the management of the neurogenic bladder. Urology. 2000 Dec 4; 56(6 Suppl 1):76-81. PMID:11114567

15. **Elliott DS**, Boone TB. Combined stent and artificial urinary sphincter for management of severe recurrent bladder neck contracture and stress incontinence after prostatectomy: a long-term evaluation. J Urol. 2001 Feb; 165(2):413-5. PMID:11176385 DOI:10.1097/00005392-200102000-00014

16. **Elliott DS**, Mutchnik S, Boone TB. The "bends" and neurogenic bladder dysfunction. Urology. 2001 Feb; 57(2):365. PMID:11182361

17. Kim IY, **Elliott DS**, Husmann DA, Boone TB. An unusual presenting symptom of sarcoidosis: neurogenic

bladder dysfunction. J Urol. 2001 Mar; 165(3):903-4. PMID:11176503

18. Petrou SP, **Elliott DS**. Artificial urethral sphincter for incontinence in adults. Drugs Today (Barc) 2001 Apr; 37(4):237-244. PMID:12768224

19. **Elliott DS**, Barrett DM, Gohma M, Boone TB. Does nocturnal deactivation of the artificial urinary sphincter lessen the risk of urethral atrophy? Urology. 2001 Jun; 57(6):1051-4. PMID:11377302

20. **Elliott DS**, Segura JW, Lightner D, Patterson DE, Blute ML. Is nephroureterectomy necessary in all cases of upper tract transitional cell carcinoma? Long-term results of conservative endourologic management of upper tract transitional cell carcinoma in individuals with a normal contralateral kidney. Urology. 2001 Aug; 58(2):174-8. PMID:11489692

21. Lightner DJ, **Elliott D**, Gillett M. Surgeon's corner. Transvaginal culdoplasty for posthysterectomy vaginal vault prolapse. Contemp Urol. 2003 Sep; 15(9):15-22. PMID:0

22. DiMarco DS, **Elliott DS**. Tandem cuff artificial urinary sphincter as a salvage procedure following failed primary sphincter placement for the treatment of post-prostatectomy incontinence. J Urol. 2003 Oct; 170(4 Part 1):1252-4. PMID:14501735

23. **Elliott DS**, Barrett DM. Current indications for the use of the artificial genitourinary sphincter and management of its complications. The Scientific World Journal. 2004; 4(S1):114-27.

24. Di Marco DS, Chow GK, Gettman MT, **Elliott DS**. Robotic-assisted laparoscopic sacrocolpopexy for treatment of vaginal vault prolapse. Urology. 2004 Feb; 63(2):373-6. PMID:14972496 DOI:10.1016/j.urology.2003.09.033

25. Dora CD, Dimarco DS, Zobitz ME, **Elliott DS**. Time dependent variations in biomechanical properties of cadaveric fascia, porcine dermis, porcine small intestine submucosa, polypropylene mesh and autologous fascia in the rabbit model: implications for sling surgery. J Urol. 2004 May; 171(5):1970-3. PMID:15076323 DOI:10.1097/01.ju.0000121377.61788.ad

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30. **Elliott DS**, Krambeck AE, Chow GK. Long-term results of robotic assisted laparoscopic sacrocolpopexy for the treatment of high grade vaginal vault prolapse. J Urol. 2006 Aug; 176(2):655-9. PMID:0

31. Routh JC, Crimmins CR, Leibovich BC, **Elliott DS**. Impact of Parkinson's disease on continence after radical prostatectomy. Urology. 2006 Sep; 68(3):575-7. Epub 2006 Sep 18. PMID:16979722 DOI:10.1016/j.urology.2006.03.025

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11. Dimarco DS, Chow GK, Gettman MT, **Elliott DS**. Robotic-assisted laparoscopic sarcocolpopexy (Abstract MP 18/17). J Endourol. 2004 Nov; 18(Suppl 1):A109.

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* Indicates that the primary author was a mentee of this author.

Compensation

I am compensated for investigation, study, and consultation in this case at the rate of $700.00 per hour.

/s/ Daniel Elliott

DANIEL ELLIOTT, M.D.

EXHIBIT B

Prior Testimony

As noted below, I have given testimony and provided expert reports in numerous Ethicon transvaginal mesh cases over the past few years. All of my testimony, opinions, and materials therein are hereby incorporated into this report by reference.

Coloplast A/S v. Generical Medical Devices; United States District Court – Western District of Washington at Tacoma Case No. C10-227BHS

Linda Gross et al. v. Gynecare, et al.; Superior Court of New Jersey Law Division – Middlesex County Case No. MID-L-9131-08– Report & Deposition

Diane Bellew v. Ethicon et al.; United States District Court, Southern District of West Virginia Case No. 2:12-cv-22473 – Report, Deposition & Trial

Janice L. St. Cyr v. C.R. Bard, Inc. et al.; United States District Court, Southern District of West Virginia Case No. 2:14-cv-02313

Kathleen Stanbrough v. C.R. Bard, Inc. et al.; United States District Court, Southern District of West Virginia Case No. 2:14-cv-06937

Sheila Sutton v. C.R. Bard, Inc. et al.; United States District Court, Southern District of West Virginia Case No. 2:14-cv-00105

Pamela Ailey v Cook Medical, Inc., et al.; United States District Court, Southern District of West Virginia Case No. 2:13-CV-20496

Patricia L. Hammons v. Ethicon, Inc., et al.; Philadelphia County Court of Common Please Case No. 0003913 – Report & De Bene Esse

Dale Watkins et al. vs. Ethicon, Inc. et al.; Superior Court of New Jersey Law Division – Bergen County Case No. BER-L-13787-14 MCL – Report & Deposition

Mullins et al v. Ethicon, Inc., et al.; Southern District of West Virginia Charleston Division Case No. 2:12-cv-02952 – Report & Deposition

EXHIBIT C

Date	Bates - Begin	Bates - End	Description
3/2/1981	ETH.MESH.15958524	ETH.MESH.15958524	Guidoin Lab Notebook Page/Image
3/17/1982	ETH.MESH.15958396	ETH.MESH.15958399	Guidoin Lab Notebook Page/Image
3/23/1983	ETH.MESH.15955438	ETH.MESH.15955473	Guidoin Lab Notebook Page/Image
3/25/1983	ETH.MESH.15958410	ETH.MESH.15958432	Guidoin Lab Notebook Page/Image
5/25/1983	ETH.MESH.15958400	ETH.MESH.15958404	Guidoin Lab Notebook Page/Image
8/14/1984	ETH.MESH.15958433	ETH.MESH.15958444	Guidoin Lab Notebook Page/Image
9/27/1984	ETH.MESH.15958408	ETH.MESH.15958409	Guidoin Lab Notebook Page/Image
11/5/1984	ETH.MESH.15958452	ETH.MESH.15958469	Guidoin Lab Notebook Page/Image
11/7/1984	ETH.MESH.15958405	ETH.MESH.15958407	Guidoin Lab Notebook Page/Image
3/11/1985	ETH.MESH.15958445	ETH.MESH.15958451	Guidoin Lab Notebook Page/Image
5/30/1985	ETH.MESH.09746373	ETH.MESH.09746448	Memo N.R. Cholvin to Dr. R.L. Kronenthal, et al. re Protocol for 10 Year In Vivo Study of Monofilament Sutures
1/20/1988	ETH.MESH.15144996	ETH.MESH.15144996	Report: Quebec Explants
1/20/1988	ETH.MESH.00004755	ETH.MESH.00004755	Guidoin Explant Study notes
8/10/1990	ETH.MESH.11336474	ETH.MESH.11336487	Five Year Report re Ten Year In Vivo Suture Study
3/8/1991	N/A	N/A	FDA Device Labeling Guidance #G91-1 (Blue Book Memo)
3/8/1991			FDA Device Labeling Guidance #G91-1
1/1/1997	ETH.MESH.00371572	ETH.MESH.00371573	Alex C. Wang "Tension-Free Vaginal Tape (TVT) for Urinary Stress Incontinence - A Preliminary Report"
2/13/1997	ETH.MESH.08696050	ETH.MESH.08696055	Consulting & Technology Agreement between Johnson & Johnson International and Professor Ulf Ivar Ulmsten
2/26/1997	ETH.MESH.08696084	ETH.MESH.08696134	Medscan Agreement
3/1/1997	N/A	N/A	Medical Device Reporting for Manufacturers by Department of Health and Human Services, Public Health Services, FDA

6/13/1997	ETH.MESH.12009095	ETH.MESH.12009101	Ulmsten Preliminary report of Multicentre Study on TVT
8/8/1997	ETH.MESH.06852120	ETH.MESH.06852129	Cytotoxicty Risk Assessment
8/29/1997	N/A	N/A	1997 Marlex MSDS
9/11/1997	ETH.MESH.09747728	ETH.MESH.09747728	Linsky email re TVT (Ulmsten) -510k submission
9/16/1997	ETH.MESH.09747632	ETH.MESH.09747643	PAC Meeting Review - Tension Free Vaginal Tape (TVT) Ulmsten Device
10/1/1997	ETH.MESH.09747724	ETH.MESH.09747725	Linsky C email re Recommendation not to Accelerate TVT Program
1/11/1998	ETH.MESH.03658577	ETH.MESH.03658577	Presentation: Biocompatibility of ULTRAPRO by Joerg L. Holste, DVM
1/28/1998	ETH.MESH.00371496	ETH.MESH.00371594	FDA 510(k) clearance letter
1/28/1998	N/A	N/A	Tension Free Vaginal Tape (TVT) System 510(k)
2/18/1998	HMRDH_ETH_00133261	HMRDH_ETH_00133262	Liu email chain re Prolene Mesh Redesign
6/17/1998	ETH.MESH.09266659	ETH.MESH.09266660	Tang email chain re Prolene Mesh Update
7/30/1998	ETH.MESH.00130934	ETH.MESH.00130941	Kaminski Memo re summary of key point from US Marketing Research Study on TVT
8/17/1998	ETH.MESH.09264945	ETH.MESH.09264946	Rousseau Memo to Lessig re Prolene Mesh Re-Design Project
8/18/1998	ETH.MESH.12009027	ETH.MESH.12009035	Rowan email re GyneMesh II New Mesh Design w/attachment
9/7/1998	ETH.MESH.09266668	ETH.MESH.09266671	Tang email chain re Mesh 3
9/17/1998	ETH.MESH.07877085	ETH.MESH.07877085	Lessig email re PROLENE Mesh Redesign Project
9/23/1998	ETH.MESH.09266465	ETH.MESH.09266466	D Aversa email chain re Prolene Mesh Sheets Research
3/30/1999	ETH.MESH.00203456	ETH.MESH.00203456	Gillick email chain re TVT insert
4/8/1999	ETH.MESH.14410703	ETH.MESH.14410741	Toth Memo to Copy Review Team re New Construction PROLENE polypropylene mesh Sales Aid and Demo Device

5/3/1999	ETH.MESH.11283974	ETH.MESH.11283974	Lehe email re Reisebericht: TVT - Brainstorming (PD 98/5)
5/4/1999	ETH.MESH.14410846	ETH.MESH.14410851	Toth email chain re New Construction PROLENE polypropylene mesh Pre-Launch Memo w/attachment
6/9/1999	ETH.MESH.11283949	ETH.MESH.11283951	Hoepffner email chain re Trip report -- meeting with Dr. Ulstem
6/24/1999	ETH.MESH.14411026	ETH.MESH.14411040	Toth, JL Memo to Copy Review Team re TVT Tension-free Vaginal Pate Press Briefing Presentation
7/13/1999	ETH.MESH.03456775	ETH.MESH.03456776	Product Pointer for TVT Tension-free Vaginal Tape
8/18/1999	ETH.MESH.09275875	ETH.MESH.09275876	Rousseau email re Samples of PROLENE Mesh
9/15/1999	ETH.MESH.04193990	ETH.MESH.04193993	Major Executive Committee Actions July 20, 1999 through September 15, 1999
12/2/1999	ETH.MESH.09346419	ETH.MESH.09346420	Memo to R. Rousseau re Biocompatibility Risk Assessment for Soft PROLENE Mesh
12/2/1999	ETH.MESH.09346417	ETH.MESH.09346418	Biocomp risk assessment GPS revised
1/4/2000	ETH.MESH.09273600	ETH.MESH.09273601	Dormier email chain re LcBlanc CME Live on Medscape
2/24/2000			Labelling for Medical Devices by SG1 and endorsed by The Global Harmonization Task Force
4/5/2000	ETH.MESH.17661347	ETH.MESH.17661347	Angleitner email chain re TVT Product complaint w/handwritten notes
4/14/2000	ETH.MESH.17661336	ETH.MESH.17661499	Hellberg communication re Product Complaint Form
4/17/2000	ETH.MESH.05529274	ETH.MESH.05529275	Gynecare TVT Tension-free Support for Incontinence
5/26/2000	ETH.MESH.06852118	ETH.MESH.06852129	Biocompatibility Review
6/1/2000	ETH.MESH.00658177	ETH.MESH.00658198	Surgeon's Resource Monograph

6/6/2000	ETH.MESH.05493965	ETH.MESH.05493999	"Meshes in Pelvic Floor Repair - Findings from literature review and conversations/interviews with surgeons" prepared by Brigitte Hellhammer
6/9/2000	ETH.MESH.00160612	ETH.MESH.00160625	Toth Memo re Gynecare TVT Tension-free Support for Incontinence Patient Education Brochure (TVT016)
7/7/2000	ETH.MESH.0137272	ETH.MESH.01137293	Incontinence/Pelvic Floor Management GYNECARE TVT Tension-free Support for Incontinence 2001 Marketing Plan
7/12/2000	ETH.MESH.01317515	ETH.MESH.01317524	TVT-2 needles Introducer Revision 8
8/14/2000	ETH.MESH.00158559	ETH.MESH.00158590	TVT Professional Education Tensioning
8/17/2000	ETH.MESH.10216874	ETH.MESH.10216875	Slusser email chain re AUGS lecture/content of discussion
8/18/2000	ETH.MESH.08793648	ETH.MESH.08793648	Study Justification: Gynecare Clinical Research Program 2001 spreadsheet
8/21/2000	ETH.MESH.03909708	ETH.MESH.03909713	ARnaud A email chain re Pelvic floor repair Procedural Strategy
8/21/2000	ETH.MESH.08793646	ETH.MESH.08793647	Isenberb email re WOW Business Plan -- 2001, Clinical Research
8/28/2000	ETH.MESH.03736578	ETH.MESH.03736578	Memo Marty Weisberg to Rick Isenberg re discussion with redacted
9/6/2000	ETH.MESH.09746615	ETH.MESH.09746617	Ltt Nilsson from Zauberman re Surgeon Panel
9/22/2000	ETH.MESH.00143697	ETH.MESH.00143699	Memo from J.L. Toth to Copy Review Team re "A three-year follow up of tension free vaginal tape for surgical treatment of the female stress urinary incontinence" Article (TVTO15 - REVIEW FOR REPRINT
9/22/2000	ETH.MESH.00143700	ETH.MESH.00143702	Memo from J.L. Toth to Copy Review Team re "A three-year follow up of tension free vaginal tape for surgical treatment of the female stress urinary incontinence" Article (TVTO15 - REVIEW FOR REPRINT

11/1/2000	ETH.MESH.03736932	ETH.MESH.03736932	Memo Marty Weisberg to Rick Isenberg re Complaint
1/16/2001	HMESH_ETH_00946830	HMESH_ETH_00946838	Dormier email chain re Corporate Product Characterization December Monthly Report
2/6/2001	HMESH_ETH_02944363	HMESH_ETH_02944364	Vypro for Pelvic Floor Repair agenda
2/13/2001	ETH.MESH.03915380	ETH.MESH.03915380	Email Axel Arnaud to Dr Uwe re Dr Lucente/TVT Procedure Improvements/Prevention of Overstretching
2/28/2001	N/A	N/A	Phillips Sumika 2001 Marlex MSDS
4/11/2001	ETH.MESH.00161129	ETH.MESH.00161130	Toth Memo re Gynecare TVT Tension-free Support for Inicontinence Competitive Mesh Products - Product Pointer
4/17/2001	ETH.MESH.00161131	ETH.MESH.00161132	Product Pointer: Gynecare TVT Tension-free Support for Incontinence: A Synthetic Sling with Erosion Rates No Higher Than Autologus Slings
4/23/2001	ETH.MESH.10181921	ETH.MESH.10181922	Ulmsten ltt Ostergard re Cannes meeting
5/14/2001	ETH.MESH.01317508	ETH.MESH.01317613	Target Sheet Design History: DH0263-DH0278
5/14/2001	ETH.MESH.02607272	ETH.MESH.02607814	Design History CH1035 (bk2) - DH1036 (bk5)
6/1/2001	ETH.MESH.05494064	ETH.MESH.05494066	Hellhammer email chain re WG: TVT instructions for use
6/1/2001	ETH.MESH.12002601	ETH.MESH.12002601	Angelini L email re TVT improvements
6/6/2001	ETH.MESH.03905472	ETH.MESH.03905477	Weisberg, M email chain re TVT recommendation from Dr. Alex Wang
6/7/2001	ETH.MESH.00144270	ETH.MESH.00144278	TVT 20010607 Gynecare TVT Tension-free Support for Incontinence
6/18/2001	ETH.MESH.08798099	ETH.MESH.08798110	2002-2003 US Marketing Plan for Gynecare TVT Tension-free Support for Incontinence
6/21/2001	HMESH_ETH.00958003	HMESH_ETH.00958005	TVT Recommendations from Dr. Wang - Meeting Minutes of June 21, 2001
6/22/2001	ETH.MESH.02089392	ETH.MESH.02089399	Scientific Advisory Panel on Pelvic Floor Repair Preliminary Minutes

6/26/2001	HMESH_ETH_00958014	HMESH_ETH_00958015	Luscombe email chain re TVT recommendations from Dr. Wang
7/3/2001	ETH.MESH.00144304	ETH.MESH.00144331	Presentation: TVT Sales Force Update @ Divisional Meeting
7/6/2001	ETH.MESH.17606501	ETH.MESH.17606502	Dormier E email chain re Vypro vs Soft Prolene Mesh for Pelvic Floor Repair
8/2/2001	ETH.MESH.00764323	ETH.MESH.00764325	5-Year Press Release Draft: Long-term Data Proves Safety and Efficacy of GYNECARE TVT Tension-free Support Treating Stress Urinary Incontinence
8/15/2001	ETH.MESH.00864131	ETH.MESH.00864133	Luscombe B email chain re Aug 11 program
9/28/2001	ETH.MESH.09306898	ETH.MESH.09306910	2002 US Marketing Plan for TVT
10/1/2001	ETH.MESH.03909721	ETH.MESH.03909733	New Products Development Gynecare Products by Axel Arnaud
1/16/2002	ETH.MESH.00029963	ETH.MESH.00029966	Luscombe email re ALERLT!!! Professional Ads for GYNECARE TVT !!!!! w/attachments
1/28/2002	ETH.MESH.04384185	ETH.MESH.04384188	Particle Release Characteristics of Clear and Blue TVT Mesh Corporate Product Characterization
1/28/2002	ETH.MESH.02613804	ETH.MESH.02613805	Corporate Product Characterization - Comparison of Particle Characteristics of Clear and 50% Blue PROLENE Mesh of TVT Device
3/28/2002	ETH.MESH.08695896	ETH.MESH.08695896	Letter from Howard Zauberman (Ethicon) to Mr. Jan Johansson (Director, Eurosund Medical AB)
4/25/2002	ETH.MESH.08793552	ETH.MESH.08793553	Email Ettore Carino to Kimberly Mullarkey re FW: DTC Review
4/25/2002	ETH.MESH.01317510	ETH.MESH.01317514	DDSA Re-Evaluation for TVT
5/1/2002	ETH.MESH.03907468	ETH.MESH.03907469	"Second Generation TVT" by Axel Arnaud
6/7/2002	ETH.MESH.03735432	ETH.MESH.03735433	Emails Richard Isenberg to Dr Wang re concerns for patient safety
6/7/2002	ETH.MESH.00409674	ETH.MESH.00409675	Email Richard Isenberg to Greg Jones, et al. re Dr Alex Wang, Taiwan--Reports of "tape rejection" with TVT

6/10/2002	ETH.MESH.03483690	ETH.MESH.03483693	Email Mark Yale re Wang's rejections
6/28/2002	ETH.MESH.01264260	ETH.MESH.01264260	Lawler T email re Polypropylene Mesh
7/2/2002	ETH.MESH.05961204	ETH.MESH.05961211	Corrective/Preventive Action TVT Tape
7/2/2002	ETH.MESH.05961197	ETH.MESH.05961203	Corrective/Preventive Action TVT Tape
7/9/2002	ETH.MESH.04927339	ETH.MESH.04927340	FDA Communication re 522 Prosima
8/8/2002	ETHMESH.OHARA.00000001	ETHMESH.OHARA.00000156	O'Hara Employment Eligibility Verification Form
8/8/2002	ETHMESH.OHARA.00000157	ETHMESH.OHARA.00000303	O'Hara personnel file docs
9/11/2002	ETH.MESH.05961212	ETH.MESH.05961234	Corrective/Preventive Action TVT Tape
9/16/2002	ETH.MESH.11773498	ETH.MESH.11773499	Email Shannon Campbell to Shelley Copeland, et al. re Ft. Worth Advanced TVT dinner feedback
9/27/2002	ETH.MESH.00030025	ETH.MESH.00030026	Letter to Dr. James Meeuwesen of Pueblo, CO from Scott Jones
10/4/2002	ETH.MESH.00409657	ETH.MESH.00409658	Rejection of Polypropylene Tape After the Tension-Free Vaginal Tape (TVT) Procedure by Alex C. Wang, MD
10/4/2002	ETH.MESH.03910208	ETH.MESH.03910210	Report: Visit to Pr Jean de Leval
12/3/2002	ETH.MESH.00409670	ETH.MESH.00409670	Email Martin Weisberg to Mark Sumeray et al. re Prolene rejection
1/9/2003	ETH.MESH.05961304	ETH.MESH.05961315	Corrective/Preventive Action TVT Tape
1/27/2003	ETH.MESH.00766975	ETH.MESH.00766976	DTC Focus Group Summary
1/31/2003	ETH.MESH.01808311	ETH.MESH.01808318	Tracey M Trip Report
2/5/2003	ETH.MESH.01808310	ETH.MESH.01808310	Tracey M email re Trip Report Format Mulberry 22Jan2003
2/13/2003	ETH.MESH.06866920	ETH.MESH.06866920	Presentation - Ultrasonic Slitting of TVT Mesh Technical Review
2/14/2003	ETH.MESH.06873447	ETH.MESH.06873458	Due Diligence Growth Opportunity Outline re Project Mulberry Next generation TVT
2/18/2003	ETH.MESH.15363068	ETH.MESH.15363085	Universite de Liege and Ethicon Licensing Agreement

2/20/2003	ETH.MESH.03911107	ETH.MESH.03911108	Arnaud A email chain re TVT complications (an Prof. Häusler)
2/28/2003	ETH.MESH.01222617	ETH.MESH.01222654	Cirellli - Histological evaluation and Comparison of Mechanical Pull Out Strength of Prolene Mesh and Prolene Soft Mesh in a Rabbit Model
3/18/2003	ETH.MESH.00581482	ETH.MESH.00581482	Osoris M email re International Convention Suggestions
3/20/2003	ETH.MESH.04205632	ETH.MESH.04205636	Strategic Plan Challenge
3/26/2003	ETH.MESH03919404	ETH.MESH03919405	Arnaud A email chain re Mulberry
4/10/2003	ETH.MESH.00858110	ETH.MESH.00858111	April 10, 2003 meeting minutes from Project Leader Dan Smith
4/14/2003	ETH.MESH.00260591	ETH.MESH.00260592	Smith,D email chain re Mulberry update
4/30/2003	ETH.MESH.03934952	ETH.MESH.03934967	TVOT Meeting report . . . de Leval, Ruel, Daoud
5/13/2003	ETH.MESH.00030098	ETH.MESH.00030098	Memo from Anthony Powell (VP, Sales) and Marianne Kaminski (Dir. of PE and Relations) to Gynecare
5/15/2003	ETH.MESH.03918552	ETH.MESH.03918553	Emails Brian Luscombe to Axel Arnaud et al. re: De Leval Publication
5/29/2003	ETH.MESH.02222437	ETH.MESH.02222656	DHF 25 1-323 CE Mark of TVT - AA Kit.pdf
5/29/2003	ETH.MESH.00863841	ETH.MESH.00863842	Study spreadsheet
6/6/2003	ETH.MESH.03907853	ETH.MESH.03907854	LeTreguilly L email chain re TVT Serious complication
6/11/2003	ETH.MESH.00764215	ETH.MESH.00764216	Russo-Jankewicz email re Stressful Secrets press release crosses wire
6/19/2003	ETH.MESH.00586018	ETH.MESH.00586019	Eltrasonic Slitting of TVT Mesh presentation
6/20/2003	ETH.MESH.05442881	ETH.MESH.05442883	Leibowitz Tensile Properties, Morphology Test Report
6/24/2003	ETH.MESH.02180737	ETH.MESH.02180737	Toddywala R email re Project Mulberry
6/30/2003	ETH.MESH.05585033	ETH.MESH.05585053	Presentation: Marketing Plan VOC by Boris Batke Project Edelweiss
7/7/2003	ETH.MESH.00030372	ETH.MESH.00030373	Email Brian Luscombe re "Urethral erosion may occur with any sling material" Article (TVT063)

7/9/2003	ETH.MESH.03715978	ETH.MESH.03715980	Email Martin Weisberg to Terry Courtney re TVT question
7/11/2003	ETH.MESH.06884249	ETH.MESH.06884250	Email Brian Luscombe to Steve Bell, et al. re Ulmsten opinion on Mulberry
7/17/2003	ETH.MESH.00865147	ETH.MESH.00865147	Arnaud email re Mulberry IFU
7/18/2003	ETH.MESH.00864085	ETH.MESH.00864087	Email Brian Luscombe to Dan Smith et al. re Design Validation
7/21/2003	ETH.MESH.03919143	ETH.MESH.03919144	Ciarrocca email chain re Gynemesh holding force in tissue
7/21/2003	ETH.MESH.06880021	ETH.MESH.06880023	Email Janice Burns to Dan Smith, et al. RE: Design Validation
7/24/2003	ETH.MESH.00864101	ETH.MESH.00864102	Smith D email chain re TOVT developments
7/25/2003			Patent CA2497158C - Devices for surgical treatment of female urinary incontinence
7/25/2003			Patent WO2004019786A1 - Devices for surgical treatment of female urinary inc
7/25/2003	N/A	N/A	Patent CA2497158C Devices for surgical treatment of female urinary incontinence
7/25/2003	N/A	N/A	Patent WO2004019786A1 - Devices for surgical treatment of female urinary incontinence
8/14/2003	ETH.MESH.01220661	ETH.MESH.01220663	Kammerer G email chain re Aug 11 program
8/15/2003	ETH.MESH.00260739	ETH.MESH.00260744	Email Brian Luscombe re Mulberry Final DRAFT #1
8/18/2003	ETH.MESH.01220693	ETH.MESH.01220697	Kammerer email chain re TVT Mesh Fraying
8/25/2003	ETH.MESH.03715869	ETH.MESH.03715876	Email Martin Weisberg to Dan Smith, et al. re Mulberry Final Draft #1
8/29/2003	N/A	N/A	2003 Marlex MSDS
9/6/2003	ETH.MESH.03738468	ETH.MESH.03738470	Email Martin Weisberg to Marianne Kaminski re TVT Response for Peggy Norton MD
9/8/2003	ETH.MESH.03928696	ETH.MESH.03928697	Arnaud A email chain re TVT complication
10/1/2003	ETH.MESH.14415287	ETH.MESH.14415309	Gynecare TVT AUGS & Competitive Update - copy review submission form

1/1/2004	ETH.MESH.00160813	ETH.MESH.00160821	Only Gynecare TVT Has Long-term Results You Can See
1/7/2004	ETH.MESH.02340829	ETH.MESH.02340901	TVT-O IFU (1/7/2004-3/4/2005)
1/16/2004	ETH.MESH.06164409	ETH.MESH.06164410	Smith D email re Dedications
1/28/2004	N/A	N/A	2004 Marlex MSDS Chevron Phillips
1/29/2004	ETH.MESH.05793690	ETH.MESH.05793693	Gynecare TVT Introduction to cross train the Uterine
2/27/2004	ETH.MESH.00863391	ETH.MESH.00863393	Smith D email chain re 2 TVT Complaints concerning allegedly brittle mesh
3/1/2004	ETH.MESH.00866317	ETH.MESH.00866318	Burns email chain re Mulberry IFU
3/2/2004	ETH.MESH.00865322	ETH.MESH.00865323	Owens C email chain re Reminder on BLUE mesh
3/3/2004	ETH.MESH.14416182	ETH.MESH.14416221	Gynecare Copy Review - Inside Gynecare Vol II, #5
3/10/2004	ETH.MESH.02619601	ETH.MESH.02619616	TVT 20040310 What you Can do about it... TVT-Stress Urinary Incontinence in Women
3/12/2004	N/A	N/A	Sunoco 2004 MSDS
3/12/2004			Sunoco 2004 MSDS
3/17/2004	ETH.MESH.14416076	ETH.MESH.14416081	Gynecare Copy Review Submission Form submitted by Giselle M. Bonett re Gynecare Gynemesh PS
3/29/2004	ETH.MESH.02180759	ETH.MESH.02180761	de Leval J memo
4/14/2004	ETH.MESH.00658058	ETH.MESH.00658065	TVT sales piece (TVT041R3)
4/19/2004	ETH.MESH.00584811	ETH.MESH.00584813	Kammerer G email re Ultrasonic Slitting of Prolene Mesh for TVT
4/19/2004	ETH.MESH.00158286	ETH.MESH.00158288	LIMS Project #: BE-2004-912 Study Report
4/27/2004	ETH.MESH.00862206	ETH.MESH.00862208	LIMS Project #: BE-2004-916
5/4/2004	ETH.MESH.05918776	ETH.MESH.05918776	Schiaparelli J email re Marlex Experience
6/30/2004	ETH.MESH.00863692	ETH.MESH.00863694	Leibowitz email re Comparison of TVT Mesh to Meshes from Competitive Devices
7/21/2004	ETH.MESH.03910799	ETH.MESH.03910800	Arnaud A email chain re TVT Erosion
7/22/2004	ETH.MESH.02201463	ETH.MESH.02201467	Email Walji to Bogardus, et al. re ICS / Paris - Gala Invitee List

8/16/2004	ETH.MESH.05456117	ETH.MESH.05456118	Email James McDivitt to Thomas Barbolt re Autoclaving PROLENE
8/17/2004	ETH.MESH.01814740	ETH.MESH.01814741	Email from Dan Smith to Katrin Elbert re IFU changes
8/18/2004	ETH.MESH.06884516	ETH.MESH.06884517	Mahar K email re Dr. Jensen Follow UP
8/27/2004	ETH.MESH.05795299	ETH.MESH.05795300	Email Marianne Kaminski to Amy Vie, et al. re 2004 budget - PE August adjustments
9/7/2004	ETH.MESH.00681364	ETH.MESH.00681366	Walji email chain re Pelvic Floor Monthly - August Report - Next Gen Materials Progress
9/11/2004	ETH.MESH.08107153	ETH.MESH.08107155	Gynecare University Program Las Vegas, Nevaga
9/23/2004	ETH.MESH.03624321	ETH.MESH.03624322	"Professional Education for GYNECARE TVT Physician Training" updated draft by Marianne Kaminski
9/24/2004	ETH.MESH.05795309	ETH.MESH.05795315	Gyncecare Mega Course Uterine Health Urodynamics Incontinence and Pelvic Floor Repair and the OB/GYN Surgeon, Urogynecologist and Urologist
10/7/2004	ETH.MESH.00031538	ETH.MESH.00031560	Sales School Presentation: Gynecare Professional Relations and Professional Education "Educating Customers Worldwide to improve the lives of women!"
11/1/2004	ETH.MESH.05548122	ETH.MESH.05548123	Smith D email re Update from Oct 27 cadaver lab
11/2/2004	ETH.MESH.01813975	ETH.MESH.01813978	Email from Patty Lancos to Manuel Castro and Dan Smith re FDA Prep
11/5/2004	ETH.MESH.03589219	ETH.MESH.03589220	MedWatch Report
12/6/2004	ETH.MESH.01217673	ETH.MESH.01217690	Development Contract TVT-Next (TVTx)
12/8/2004	ETH.MESH.08003197	ETH.MESH.08003212	TVT 20041208 Gynecare TVT Tension-free Support for Incontinence Patient Brochure reprint /Robin Osman
1/3/2005	ETH.MESH.05768705	ETH.MESH.05768712	2005 Variable Compensation Plan Sales Representative

1/5/2005	ETH.MESH.00440005	ETH.MESH.00440007	Email Laura Angelini to Ronnie Toddywala, et al. re Important Laser cut mesh Update
1/17/2005	ETH.MESH.00585220	ETH.MESH.00585220	Kammerer email re Presentation #1
1/18/2005	ETH.MESH.07931874	ETH.MESH.07931886	Hojnoski Personnel File
1/19/2005	ETH.MESH.02248778	ETH.MESH.02248778	Presentation: Mechanical vs. "Machine"-cut Mesh
1/19/2005			Mechanical v "Machine" - cut Mesh Prepared by Allison London Brown, Gene Kammerer
1/27/2005	N/A	N/A	United States Patent Application Publication De Leval US20050021086 20050127
1/27/2005	ETH.MESH.05553782	ETH.MESH.05553782	Smith email re TVT-U
1/27/2005			US Patent Application Publication US20050021086 20050127
1/28/2005	ETH.MESH.08792936	ETH.MESH.08792938	Carino email chain re Recommendations for Non-Sales and Marketing Glamour Trip Award
1/30/2005	ETH.MESH.11474337	ETH.MESH.11474337	Castillo email chain re Oscar -- The latest fiasco
2/1/2005	ETH.MESH.00524907	ETH.MESH.00524907	Presentation: TVT Bonnie Blair Campaign
2/2/2005	ETH.MESH.00162420	ETH.MESH.00162421	TVT Mailers for Physicians
2/2/2005	ETH.MESH.14410478	ETH.MESH.14410484	McCabe Gynecare TVT Mesh Brochure copy review submission form
2/11/2005	ETH.MESH.02340471	ETH.MESH.02340503	TVT IFU through
2/16/2005	ETH.MESH.14409737	ETH.MESH.14409741	Copy review submission form - Hernia ad; Proceed Mesh. ULTRAPRO mesh and PROLENE hernia system
2/28/2005	ETH-03531	ETH-03567	Everett J Summary Memo for Revision C of the Gynecare PROLIFT Device Design Safety Assessment
3/1/2005	ETH.MESH.03574916	ETH.MESH.03574919	Email Charlotte Owens to Carol Holloway re Medical Review file #30005136
3/10/2005	ETH.MESH.03499528	ETH.MESH.03499529	Berger L ltt Wallingford J re Unknown TVT Ref #3005146
3/10/2005	ETH.MESH.05245427	ETH.MESH.05245428	Next Generation Mesh Discussion

3/15/2005	HMESH_ETH_01876389	HMESH_ETH_01876393	Oldelehr M email chain re Kalamazoo TVT Business at Risk
3/24/2005	ETH.MESH.06828907	ETH.MESH.06828909	Hunsicker email chain re ICS Submission
4/5/2005	ETH.MESH.03575061	ETH.MESH.03575061	Email Charlotte Owens to Carin Rassier re Complaint 30005255
4/12/2005	ETH.MESH.03915588	ETH.MESH.03915590	Kammerer, G email chain re Ultrapro
4/13/2005	ETH.MESH.00994917	ETH.MESH.00994918	Barbara McCabe email re Sheath Sales Tool
4/13/2005	ETH.MESH.02026591	ETH.MESH.02026595	Sunco C4001 Polypropylene Homopolymer MSDS
4/13/2005	ETH.MESH.00658421	ETH.MESH.00658429	TVT 20040413 Gynecare TVT Tension-free Support for Incontinence Patient Education Brochure/Robin Osman
4/13/2005	ETH.MESH.05469908	ETH.MESH.05469912	Barbolt, T email chain re Ultrapro
4/13/2005	ETH.MESH.05795322	ETH.MESH.05795324	Emails Marianne Kaminski to Paul Parisi, et al. re Q1 PE results REVISED
4/13/2005	ETH.MESH.02614599	ETH.MESH.02614603	Corporate Product Characterization Protocol to Evaluate Elongation, Particle Loss and Flexural Rigidity of TVT U PROLENE Mesh Laser-Cut vs Mechanical-Cut Version 1
4/13/2005	ETH.MESH.04020134	ETH.MESH.04020137	Holste, J email chain re Ultrapro
4/14/2005	ETH.MESH.03915567	ETH.MESH.03915572	Toddywala, R email chain re Ultrapro
4/29/2005	ETH.MESH.05549696	ETH.MESH.05549700	Komamycky P email chain re Bio compatibility samples
5/5/2005	ETH.MESH.06696367	ETH.MESH.06696379	Seppa K Memo re Performance Evaluation of TVT U Prolene Mesh: Mechanical Cut versus Laser Cut STudy (LIMS#BE-2005-1920) Version 3
5/6/2005	ETH.MESH.00526473	ETH.MESH.00526474	London Brown A email re Laser-cut Mesh
5/25/2005	ETH.MESH.02627466	ETH.MESH.02627466	TVT Retropubic Issue Report No. 30005181
6/1/2005	ETH.MESH.08107933	ETH.MESH.08107933	Oldelehr email re gynecology vs urology

6/3/2005			Labelling for Medical Devices by SG1 and endorsed by The Global Harmonization Task Force
6/6/2005	ETH.MESH.02020712	ETH.MESH.02020713	Zaddem V email chain re MINT: 6/2/05 Materials Advisory meeting minutes
6/28/2005	ETH.MESH.19356913	ETH.MESH.19356915	Objectives for Jennifer - May-August
7/19/2005	ETH.MESH.00412260	ETH.MESH.00412269	Clinical Study Agreement between Dr. Douglas Grier and Ethicon
8/16/2005	ETH.MESH.00525573	ETH.MESH.00525573	London Brown A email re TVT Laser Cut Mesh
8/23/2005	ETH.MESH.04985249	ETH.MESH.04985252	Email Paula Evans to Sungyoon Rha et al. re TVT Laser Cut Value Proposition and Forecast
8/24/2005	ETH.MESH.00525322	ETH.MESH.00525400	Gynecare TVT Professional Education Slides
8/29/2005	ETH.MESH.12933182	ETH.MESH.12933183	Physician form letter
9/1/2005	ETH.MESH.03605398	ETH.MESH.03605402	Consulting Agreement B-1 between Brian J. Flynn and Ethicon
11/4/2005	ETH.MESH.09268506	ETH.MESH.09268508	Rousseau, R email chain re Gynemesh PS w/Monocryl
1/15/2006	ETH.MESH.00134498	ETH.MESH.00134499	Miller email chain re GYNECARE TVT Latest Complication Data
1/15/2006	ETH.MESH.00756887	ETH.MESH.00756888	Email Dennis Miller to Dharini Amin et al. re Gynecare TVT Latest Complication Data
1/19/2006	ETH.MESH.03908029	ETH.MESH.03908031	Van Dijk email chain re Ti-mesh research
1/20/2006	ETH.MESH.1218594	ETH.MESH.1218596	London Brown email chain re TVT U Completion Report Version 3
1/26/2006	ETHMESH.OHARA.00000315	ETHMESH.OHARA.00000321	Vandenburgh 2005 Performance and Development Plan Summary for Christopher O'Hara
1/31/2006	ETH.MESH.03911712	ETH.MESH.03911715	Arnaud A email chain re TVT - TVT-O Specifications
2/1/2006	ETH.MESH.00394544	ETH.MESH.00394553	Global Regulatory Strategy GYNECARE TVT - Laser Cutting Project
2/6/2006	ETH.MESH.00847536	ETH.MESH.00847536	Robinson email chain re TVT complications

2/15/2006	ETH.MESH.00584291	ETH.MESH.00584292	Flatow J email chain re DVer protocol for particle loss
2/20/2006	ETH.MESH.03929173	ETH.MESH.03929177	Arnaud email chain re TVM discussions
2/23/2006	ETH.MESH.00302390	ETH.MESH.00302392	Memo Dan Lamont re TVT-Base & TVT-O Complaint Review for Laser Cut Mesh (LCM) Risk
2/23/2006	ETH.MESH.00330760	ETH.MESH.00330764	Email Cindy Crosby to Mark Yale, et al. re MHRA request - TVT blue pigment risk assessment
2/24/2006	ETH.MESH.00302105	ETH.MESH.00302106	Lamont D Memo re TVT Laser Cut Mesh Risk Analysis Summary
2/24/2006	ETH.MESH.10984358	ETH.MESH.10984359	Lamont D Memo re TVT Laser Cut Mesh (LCM) Risk Analysis Summary
2/28/2006	ETH.MESH.00846523	ETH.MESH.00846523	Robinson email re tvt - training
3/1/2006	ETH.MESH.00134029	ETH.MESH.00134031	Mahar email chain re Urgent Request: Revised TVt Complication data 2-9-06
3/2/2006	ETH.MESH.04122262	ETH.MESH.04122264	Email Dr. James Hart to David Robinson re tvt o training
3/6/2006	ETH.MESH.01222075	ETH.MESH.01222079	Kammerer memo re Elongation Characteristics of Laser Cut PROLENE Mesh for TVT
3/6/2006	ETH.MESH.03358398	ETH.MESH.03358402	Kammerer G Memo to Weisbert and Robinson re Elongation Characteristics of Laser Cut PROLENE Mesh for TVR
3/7/2006	ETH.MESH.01784823	ETH.MESH.01784828	Clinical Expert Report for Laser Cut Mesh signed by Martin Weisberg, MD and David Robinson MD
3/7/2006	ETH.MESH.01221735	ETH.MESH.01221740	Weisberg, Robinson Clinical Expert Report
3/9/2006	ETH.MESH.01221618	ETH.MESH.01221619	Kammerer G email chain re Elongation properties of LCM
3/10/2006	ETH.MESH.11920108	ETH.MESH.11920110	Urology University March 10-11, 2006
3/10/2006	ETH.MESH.00585672	ETH.MESH.00585673	Next Generation Mesh Discussion Agenda
3/13/2006	ETH.MESH.05446127	ETH.MESH.05446128	Holste J email chair re Mesh and Tissue Contraction in Animal

3/20/2006	ETH.MESH.01219984	ETH.MESH.01219994	Flatow Completion Report for Design Verification of TVT Laser Cut Mesh
3/22/2006	ETH.MESH.00169748	ETH.MESH.00169751	TVT Slim Jim (TVT107)
3/29/2006	ETH.MESH.00302181	ETH.MESH.00302184	Email Daniel Lamont to Jacqueline Flatow re TVT LCM - design inputs
3/30/2006	ETH.MESH.01945854	ETH.MESH.01945854	Email Mark Yale re TVT laser cut equivalency
3/30/2006	ETH.MESH.00700348	ETH.MESH.00700350	Gadot email chain re Laser Cut Mesh Positioning (Redacted)
4/2/2006	ETH.MESH.06040171	ETH.MESH.06040173	Mahar K email chain re Laser Cut Mesh Positioning
4/7/2006	ETH.MESH.05222673	ETH.MESH.05222705	TVT IFU through
4/17/2006	ETH.MESH.14450438	ETH.MESH.14450442	Kammerer G Memo re Justification for Utilizing the Elasticity Test as the Elongation Requirements on TVT Laser Cut Mesh
4/18/2006	ETH.MESH.00998349	ETH.MESH.00998355	Weisberg M and Robinson D CER
4/18/2006	ETH.MESH.00167104	ETH.MESH.00167110	CER Weisberg - Laser Cut Mesh
4/25/2006	ETH.MESH.06696589	ETH.MESH.06696592	Minute - Tactile appraisal of TVT LCM & LCM-MC both vs MCM
4/26/2006	ETH.MESH.10302266	ETH.MESH.10302267	Damotte email chain re Laser cut TVT - Surgeon's Preference Evaluation
5/1/2006	ETH.MESH.03358217	ETH.MESH.03358224	Kammerer G email chain re French Standard on TVT & Meshes (Comments required)
5/4/2006	ETH.MESH.01221024	ETH.MESH.01221025	Kammerer G email re New Standards for Urethral Slings
5/9/2006	ETH.MESH.01816990	ETH.MESH.01816990	Mesh development timeline
5/9/2006	ETH.MESH.00585802	ETH.MESH.00585802	Kammerer G email re Particle loss of TVT
5/9/2006	ETH.MESH.01219629	ETH.MESH.01219630	Flatow J email chair re Particle loss on TVT
5/22/2006	ETH.MESH.00584175	ETH.MESH.00584178	Sungyoon Rha email re First Human Use - Surgeon preference Questionnarie
5/22/2006	HMESH_ETH_01840151	HMESH_ETH_01840152	"World Premiere" as Ethicon Women's Health & Urology with special guest Bonnie Blair

5/31/2006	ETH.MESH.04321670	ETH.MESH.04321681	Visual Acceptance Criteria for Blister Sealing; VSE0007, Revision: D
6/2/2006	ETH.MESH.00870466	ETH.MESH.00870476	Expert Meeting Minutes - Meshes for Pelvic Floor Repair
6/12/2006	ETH.MESH.00585842	ETH.MESH.00585843	Kammerer G email chain re TVT LCM - particle loss (reimbursement submission)
6/13/2006			T 213 om-01 Proposed Revision - Dirt in pulp - chart method
6/14/2006	ETH.MESH.03274663	ETH.MESH.03274670	Email Marie-Ange Damotte to Sungyoon Rha, et al. re TVT Laser Cut First Human Use - surgeon preference questionnaire
6/15/2006	ETH.MESH.08164248	ETH.MESH.08164256	Company Procedure for US Regulatory Affairs Review of Promotion and Advertising Materials for Medical Devices
6/22/2006	ETH.MESH.00998347	ETH.MESH.00998347	Gadot, Harel email re LCM - Launch Strategy EMEA
6/22/2006			Gadot, H EMEA Launch Strategy
6/23/2006	ETH.MESH.00526484	ETH.MESH.00526487	St. Hilaire P email chain re LCM - Launch Strategy EMEA
6/26/2006	ETH.MESH.00167119	ETH.MESH.00167119	Product Pointer: Gynecare TVT Tension-free Support for Incontinence -- available in laser cut mesh
6/27/2006	ETH.MESH.00585823	ETH.MESH.00585832	Kammerer email chain re URHENTFrench STANDARD ON TVT & Meshes
7/17/2006	ETH.MESH.08003215	ETH.MESH.08003230	TVT 20060717 Patient Brochure - Find out how to stop urine leakage like Bonnie did
7/20/2006	ETH.MESH.00311802	ETH.MESH.00311804	Email Paula Evans to David Robinson et al. re TVT dataMcNelis, Linda
8/1/2006	ETH.MESH.05454207	ETH.MESH.05454207	Jürgen email re Fotos cadeavar lab
8/13/2006	ETH.MESH.00870481	ETH.MESH.00870482	London Brown, A email chainre LIGHTning clinical strategy
8/28/2006	ETH.MESH.06001408	ETH.MESH.06001408	ICM Project Presentation

8/29/2006	ETH.MESH.00584527	ETH.MESH.00584527	Second half photo presentation. ppt
9/27/2006	ETH.MESH.08003231	ETH.MESH.08003246	TVT016R6 Patient brochure - Find out how to stop urine leakage like Bonnie did
10/4/2006	ETH.MESH.00746204	ETH.MESH.00746208	Hernandez J email re TVT LCM Early EU Feedback
10/9/2006	ETH.MESH.00524059	ETH.MESH.00524060	Email Cheryl Bogardus to Dharini Amin re TVT 10 year anniversary/10 year data from Nillson
1/2/2007	ETH.MESH.00161512	ETH.MESH.00161513	TVT sales piece (TVTS004)
1/23/2007	ETHMESH.OHARA.00000322	ETHMESH.OHARA.00000327	Qually 2006 Performance and Development Plan Summary for O'Hara
2/6/2007	ETH.MESH.00722339	ETH.MESH.00722349	St. Hilaire email chain re OBGYN Department Members. Due to the potential serious implications . . .
2/6/2007	ETH.MESH.00719198	ETH.MESH.00719209	Mahar email chain re hospital concern from medico-legal standpoint
2/7/2007	ETH.MESH.02316434	ETH.MESH.02316436	Robinson email chain re PLEASE DO NOT DISTRIBUTE THIE EMAIL!!! . . .broadcase bulletin re Dr. Levy
2/9/2007	ETH.MESH.05475773	ETH.MESH.05475822	Presentation: The (clinical) argument of lightweight mesh in abdominal surgery by Boris Batke
2/20/2007	ETH.MESH.00303084	ETH.MESH.00303085	Lamont D email chain re Complaint Summaries
2/23/2007	ETH.MESH.02017152	ETH.MESH.02017158	Ethicon Expert Meeting: Meshes for Pelvic Floor Repair brochure
2/23/2007	ETH.MESH.01782867	ETH.MESH.01782867	Factors Related to Mesh Shrinkage: What do we know? A review of literature and internal studies
3/20/2007	ETH.MESH.00539862	ETH.MESH.00539898	TVT-World-Wide Observational Registry for Long-Term Data
4/5/2007	ETH.MESH.01218361	ETH.MESH.01218367	Spychaj K memo re Shrinking meshes
4/17/2007	N/A	N/A	United States Patent De Leval US7204802
4/17/2007			US7204802 - US Patent De Leval

5/4/2007	HMESH_ETH_06509815	HMESH_ETH_06509817	Timmer message re updated Mesh Shrinkage Discussion meeting w/attachments
5/11/2007	ETH.MESH.00136359	ETH.MESH.00136359	Email Price St. Hilaire to Dr Kavaler re AUA in Booth Activities
5/31/2007	ETH.MESH.08003263	ETH.MESH.08003278	Marketing Brochure - One day you have urine lekage. The next day you don't. End of Story.
6/1/2007	ETH.MESH.03913651	ETH.MESH.03913665	CDMA Eurpoe Meeting Urinary Incontinence Platform minutes June 1, 2007
7/6/2007	ETH.MESH.05447475	ETH.MESH.05447476	Engel D email chain re How inert is polypropylene?
7/6/2007	ETH.MESH.05447481	ETH.MESH.05447482	Barbolt email chain re How inert is polypropylene
7/9/2007	ETH.MESH.05588123	ETH.MESH.05588126	Wohlert S email chain re How inert is polypropylene?
7/20/2007	ETH.MESH.05920616	ETH.MESH.05920617	Chomiak M email re Defining light weight mesh
8/31/2007	ETH.MESH.00844341	ETH.MESH.00844344	Robinson D email Chain re Asking TVT Complication? - Fraying
9/24/2007	ETH.MESH.06214296	ETH.MESH.06214300	EPC131 Revision A Neuchatel Prolift+M Product Specification
9/27/2007	ETH.MESH.02114101	ETH.MESH.02114103	Osman email chain re Wal-Mart Female Pelvic Health Poster Options
10/5/2007	ETH.MESH.06372356	ETH.MESH.06372363	Global Harms List Document for Review & Comment by Medical Affairs Personnel
10/9/2007	N/A	N/A	2007 Marlex MSDS
11/1/2007	N/A	N/A	FDA Science and Mission at Risk -- Report from Subcommittee on Science and Technology
1/8/2008	ETH.MESH.03509909	ETH.MESH.03509910	Flores email chain re New complaint acknowledgement/request for info 10100062684
1/9/2008	ETH.MESH.04127133	ETH.MESH.04127134	Maree, A email chain re TGA Meeting
2/4/2008	ETHMESH.OHARA.00000328	ETHMESH.OHARA.00000333	Ullmann 2007 Performance and Development Plan Summary for O'Hara
2/7/2008	ETH.MESH.16416002	ETH.MESH.16416004	Kahlson H email chain re Conversion to Laset Cut TVT

2/8/2008	ETH.MESH.08692660	ETH.MESH.08692667	Master Consulting Agreement between Ethicon (signed by Price St. Hilaire) and Carl Nilsson
2/19/2008	ETH.MESH.00057336	ETH.MESH.00057374	Pelvic Floor Sumit
2/22/2008	ETH.MESH.01775242	ETH.MESH.01775257	Executive Summary - Preliminary results of peri-operative and 3-month outcomes from a world-wide observational registry of tension-free vational tapes in with with SUI
3/3/2008	ETH.MESH.01279975	ETH.MESH.01279976	Gadot H email re Next step in SUI sling
3/3/2008	ETH.MESH.00328895	ETH.MESH.00328901	Robinson D email chain re Quality issue with a batch of gynemesh
3/4/2008	ETH.MESH.02293673	ETH.MESH.02293677	Gadot H email chain re Next step in SUI Sling
3/5/2008	ETH.MESH.00303944	ETH.MESH.00303945	Lamont D email chain re Gynemesh issue
3/19/2008	ETH.MESH.03614158	ETH.MESH.03614158	Email Kyung Yu to Susie Chilcoat re Flynn preceptorships
3/26/2008	ETH.MESH.03458123	ETH.MESH.03458138	Bonnie Blair - Find out how to stop uring leakage like Bonnie did
4/15/2008	ETH.MESH.03916716	ETH.MESH.03916727	Notes
4/15/2008	ETH.MESH.02090196	ETH.MESH.02090209	Trip Notes
4/15/2008	ETH.MESH.09909642	ETH.MESH.09909655	Trip Notes
4/15/2008	ETH.MESH.15433760	ETH.MESH.15433773	Trip Notes
4/16/2008	ETH.MESH.10003595	ETH.MESH.10003603	Notes - Post Mini TVT Procedure Discussion
4/23/2008	ETH.MESH.03916715	ETH.MESH.03916715	Hernandez email chain re Liege Trip Notes. doc
4/29/2008	ETH.MESH.00304013	ETH.MESH.00304014	Lamont D email chain re Post Launch Reviews
5/5/2008	ETH.MESH.03914629	ETH.MESH.03914630	Arnaud email chain re sling business for SUI
5/16/2008	ETH.MESH.00345289	ETH.MESH.00345291	Email Krystina Laguna to Price St. Hilaire re Copy Review TVT Complications
6/4/2008	ETH.MESH.00057335	ETH.MESH.00057335	Linton email re AUGS attendees
6/6/2008	ETH.MESH.00355003	ETH.MESH.00355007	Nilsson, et al. "Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence"
6/18/2008	ETH.MESH.04048515	ETH.MESH.04048520	Carl G. Nilsson KOL Interview

7/29/2008	ETH.MESH.09004550	ETH.MESH.09004553	Kadadkia R email chain re TVT LCM - launch delay due to OQ failure
8/14/2008	ETH.MESH.03459088	ETH.MESH.03459104	TVT Brochure "The Choice to End Stress Urinary Incontinence. Find out how to stop urine leakage like Bonnie did"
8/27/2008	ETH.MESH.09504568	ETH.MESH.09504571	Scavona email chain re PQI TVT S
8/27/2008	ETH.MESH.09504558	ETH.MESH.09504559	Brennan email chain re TVT-S Mesh Torn Complaint Review for Wednesday morning Conf Call
9/5/2008	ETH.MESH.03459211	ETH.MESH.03459212	FOR IMMEDIATE RELEASE: New Study Offers More Than a Decade of Evidence for Minimally-Invasive Surgery to Treat Female Incontinence
9/24/2008	ETH.MESH.04099233	ETH.MESH.04099234	Email Melissa Day to Meng Chen, et al. re #10100078150
9/24/2008	ETH.MESH.19354118	ETH.MESH.19354119	Email Marcus Oldelehr to Brian Flynn re Flynn visit 10/23
9/25/2008	ETH.MESH.03914909	ETH.MESH.03914909	Arnaud A email re TVT World registry
9/25/2008	ETH.MESH.00164643	ETH.MESH.00164648	TVT sales piece
12/4/2008	N/A	N/A	2008 Marlex MSDS
12/9/2008	ETH.MESH.01673341	ETH.MESH.01673341	Presentation: "Stop Coping. Start Living. Treatment Options for Urinary Incontinence."
1/1/2009	ETHMESH.OHARA.00000340	ETHMESH.OHARA.00000346	2009 Performance and Development Plan Summary for Christopher O'Hara
1/7/2009	ETH.MESH.01202101	ETH.MESH.01202103	Kirkemo A email chain re My revised writeup of the DeLeval and Waltregny Visit
1/7/2009	ETH.MESH.03916905	ETH.MESH.03916913	Hinoul P email chain re My revised writeup of the DeLeval and Waltregny visit
1/7/2009	ETH.MESH.09955474	ETH.MESH.09955479	Total Petrochemicals Certificate N° 9
1/23/2009	ETH.MESH.04050265	ETH.MESH.04050267	Hinoul memo re meeting with Prof DeLeval and Prof Waltregny
1/26/2009	ETH.MESH.11985160	ETH.MESH.11985164	Issue Report

1/28/2009	ETH.MESH.07181044	ETH.MESH.07181044	Urquhart email re TVT World AE Report w/attachment
1/28/2009	ETH.MESH.03208548	ETH.MESH.03208549	Hinoul P email chain re TVT World AE Report
1/29/2009	ETH.MESH.04094863	ETH.MESH.04094864	Emails Bryan List to Meng Chen et al. re TVT IFUs on tape extrusion, exposure and erosion
1/29/2009	ETH.MESH.04093125	ETH.MESH.04093125	Chen M email re TVT IFUs on tape extrusion, exposure and erosion
2/6/2009	ETH.MESH.00007091	ETH.MESH.00007091	Haby email re CR Approved 2009-98
2/16/2009	N/A	N/A	IUGA 2009 Ital Sponsorship Invoice - 34th Annual Meeting Como, Italy June 10-20, 2009
2/23/2009	ETH.MESH.07383730	ETH.MESH.07383731	Zipfel R email chain re Ultrapro mesh info
2/25/2009	ETH.MESH.03208738	ETH.MESH.03208738	Email Jason Hernandez re Quick Response Needed to Finalize TVT WORLD Recommendation for Board Meeting on Monday Mar 2nd
2/27/2009	ETH.MESH.09951746	ETH.MESH.09951747	Ciarrocca email chain re MiniMe discussion at the board meeting
3/2/2009	ETH.MESH.00827376	ETH.MESH.00827379	Hernandez J email chain re EWHU Board recommendation
3/6/2009	ETH.MESH.09951087	ETH.MESH.09951090	Ciarrocca email re Sling thoughts and next steps 11-13-08.doc
3/6/2009	ETH.MESH.03966039	ETH.MESH.03966040	Emails Scott Finley to Melissa Chaves re Fast Break Update
3/9/2009	ETHMESH.OHARA.00000334	ETHMESH.OHARA.00000339	Ullmann 2008 Performance and Developmnet Plan Summary for Christopher O'Hara
3/11/2009	ETH.MESH.00339053	ETH.MESH.00339057	Physican brochure/sales aid "Make Data and Safety your Choice"
3/11/2009	ETH.MESH.00590896	ETH.MESH.00590897	Hinoul P email re EJOGTB-08-4159R1 - Minor Revision
3/19/2009	ETH.MESH.06040657	ETH.MESH.06040658	Mahar email chain re Credo debrief
3/20/2009	ETH.MESH.00407285	ETH.MESH.00407285	Letter Patricia Beach (Ethicon) to Dr. Douglas Grier re TVT World Registry

4/1/2009	ETH.MESH.00346227	ETH.MESH.00346227	Lisa B email re TVT-Mini clinical support
4/8/2009	ETH.MESH.00591127	ETH.MESH.00591128	Hinoul email chain re registry for all!
4/8/2009	ETH.MESH.05238373	ETH.MESH.05238374	Hinoul email chain re Tensile Properties of POP Mesh
4/9/2009	ETH.MESH.05238382	ETH.MESH.05238384	Jones, S email re Tensile Properties of POP Mesh
4/20/2009	ETH.MESH.01238552	ETH.MESH.01238553	Piet Hinoul letter re meeting with Prof deLeval and Prof Waltregny
4/22/2009	ETH.MESH.01238538	ETH.MESH.01238541	Email Piet Hinoul to Dan Smith re Meeting Minutes Prof deLeval 20/04/09
4/22/2009	ETH.MESH.03917298	ETH.MESH.03917300	Email Piet Hinoul to Katrin Elbert et al. re Meeting Minutes Prof deLeval 20/04/09
4/22/2009	ETH.MESH.01238551	ETH.MESH.01238551	Email Piet Hinoul to Katrin Elbert et al. re Meeting Minutes Prof deLeval 20/04/09
4/24/2009	ETH.MESH.03259439	ETH.MESH.03259440	Email Judi Gauld to Colin Urquhart re green journal
4/28/2009	ETH.MESH.00533250	ETH.MESH.00533256	TVT-World-Wide Observational Registry for Long-Term Data
4/30/2009	ETH.MESH.06928168	ETH.MESH.06928168	Email Henri Decloux to Valerie Emperado re T-Con follow up
5/15/2009	ETH.MESH.09957926	ETH.MESH.09957927	Email Katrin Elbert to Henri Decloux re Last week's Medi-Line visit
5/20/2009	ETH.MESH.15285672	ETH.MESH.15285672	Email Stale Kvitle to Jean DeLeval, et al. re Mini Me follow up from our visit
5/26/2009	ETH.MESH.02122903	ETH.MESH.02122905	Brennan email chain re TVT Complications Statement 2008
5/26/2009	ETH.MESH.06806078	ETH.MESH.06806092	F 2097 - 08 Standard Guide for Packaging of Medical Products
5/26/2009	ETH.MESH.02250914	ETH.MESH.02250945	All Active CAPA's
6/3/2009	ETH.MESH.04314739	ETH.MESH.04314740	Chaves email re Fast Break Promotion Update
6/11/2009	ETH.MESH.14442958	ETH.MESH.14442976	Divilio Memo re The Use of Mesh in Hernia Repair
6/19/2009	ETH.MESH.10630809	ETH.MESH.10630813	Sunoco MSDS 2009

6/26/2009	ETH.MESH.08007248	ETH.MESH.08007249	Email Brian Flynn to Jonathan Fernandez re Contracted Pricing
6/29/2009	ETH.MESH.07402878	ETH.MESH.07402879	Email Michelle Hurley to Jackie Sauer re SBT Meeting
7/1/2009	ETH.MESH.00139845	ETH.MESH.00139867	AdvaMed Code of Ethics on Interactions with Healthcare Professionals
7/15/2009	ETH.MESH.10133116	ETH.MESH.10133116	Email Brian Langen to Vincenza Zaddem re Plus-M payment for Mel Anhalt
7/16/2009	ETH.MESH.01239065	ETH.MESH.01239066	Robinson D email chain re TVT RR IFU Version 5 071409_T-3466
7/28/2009	ETH.MESH.06239100	ETH.MESH.06239108	Bobertz email chain re URGENT: Resin information request
7/30/2009	ETH.MESH.03656697	ETH.MESH.03656699	Email Takahito Hino to Patrice Napoda re TVT Japanese Package Insert
8/1/2009	ETH.MESH.10233144	ETH.MESH.10233148	2009 Field Visit Letter
8/7/2009	ETH.MESH.09958050	ETH.MESH.09958051	Email Henri Decloux to Severine Timoner Fortin re Quote for sample production
8/7/2009	ETH.MESH.09951106	ETH.MESH.09951107	Email Severine Timoner Fortin to Valerie Emperado et al. re For Information - lot of TVT used for Deleval's tests
8/8/2009	ETH.MESH.09954485	ETH.MESH.09954486	Hinoul email chain re For Information - lot of TVT used for Deleval's tests
8/12/2009			US Patent Application Publication De Leval US20090306459
8/12/2009	N/A	N/A	United States Patent Application Publication De Leval US20090306459
8/17/2009	ETH.MESH.10227358	ETH.MESH.10227359	Prine email chain re TVT promotion Slam Dunk Winners
8/21/2009	ETH.MESH.02596464	ETH.MESH.02596467	Email David Waltregny to Piet Hinoul re TR: For Information - lot of TVT used for Deleval's tests
8/27/2009	ETH.MESH.09955464	ETH.MESH.09955464	Timoner Fortin email re Mini-O Raw material proposed by Suppliers for button aid

9/14/2009	ETH.MESH.00592915	ETH.MESH.00592916	Savidge S email chain re TVT RR IFU 090911b_T-3467
9/17/2009	ETH.MESH.03722384	ETH.MESH.03722386	Email Paul DeCosta to Thomas Divilio, et al. re: Mesh + Anti-proliferative agent
9/28/2009	ETH.MESH.03618587	ETH.MESH.03618596	Master Consulting Agreement between Brian J. Flynn and Ethicon
9/29/2009	ETH.MESH.00533283	ETH.MESH.00533286	Communication Plan to close TVT World Registry
11/3/2009			United States Patent De Leval US7611454
11/3/2009	N/A	N/A	United States Patent De Leval US7611454
1/4/2010	ETH.MESH.03832685	ETH.MESH.03832692	Monthly Closed CAPA
1/5/2010	ETH.MESH.00077727	ETH.MESH.00077732	Timoner Fortin, S email chain re Prosima learning's at preceptor sites EMEA
1/8/2010	ETH.MESH.00340990	ETH.MESH.00340999	Global Regulatory Strategy for TVT IFU (RMC P15506/E) Update (Part II, RA0001-2010, Rev. 0) by Susan Lin to John Young
1/17/2010	ETH.MESH.01785259	ETH.MESH.01785260	Hinoul, P email chain re +M relaxation
1/21/2010	ETH.MESH.09234953	ETH.MESH.09234954	TVT Matketing email re 2010 Planning -- "Voice of the Customer" feedback
1/27/2010	ETH.MESH.00349508	ETH.MESH.00349512	TVT ad "Demand the most proven technology when selecting a mid-urethral sling... Make DATA and SAFETY YOUR CHOICE"
1/28/2010	ETH.MESH.09234951	ETH.MESH.09234952	Flores email chain re Continence Health Brand Team - TVT Feedback
2/6/2010	ETH.MESH.01805963	ETH.MESH.01805963	Peebles R email re Mesh slides for NTM
2/16/2010	ETH.MESH.09235084	ETH.MESH.09235085	Toglia M email chain re Ethicon Women's Health and Urology National Training meeting - TVT
2/17/2010	ETH.MESH.00340839	ETH.MESH.00340839	Gynecare TVT Device Instructions for Use Revision Design Verification Memo by Kirkemo, Robinson and Hinoul
2/19/2010	ETH.MESH.02254087	ETH.MESH.02254087	Beath C email re clinical data
2/24/2010	ETH.MESH.08014324	ETH.MESH.08014327	Email Jonathan Fernandez to Carol Padgett re Dr. Alvina Driscoll

2/25/2010	ETH.MESH.00073089	ETH.MESH.00073093	Robinson D email chain re 510k submission and clearance
2/26/2010	ETH.MESH.00659430	ETH.MESH.00659431	Physician brochure/sales aid
2/27/2010	ETH.MESH.09214438	ETH.MESH.09214438	Peebles email re participation next week - copy-approved slides
3/4/2010	ETH.MESH.16263696	ETH.MESH.16263715	EWHU 2009 Awards Ceremony
3/10/2010	ETH.MESH.00074068	ETH.MESH.00074070	Savidge S and Johnson L - biocompatiblity statement
3/17/2010	ETH.MESH.19306944	ETH.MESH.19306946	Ullman email chain re "Take Back Share" - Feb Update
3/19/2010	ETH.MESH.01201387	ETH.MESH.01201389	Bryan L email chain re EBM Sub-team meetings for EWHU
3/23/2010	ETH.MESH.00351439	ETH.MESH.00351441	Smith D email chain re Input to the one-pager to BR
3/24/2010	ETH.MESH.09932848	ETH.MESH.09932849	Iacobone email chain re Stability Testing
3/25/2010	ETH.MESH.02013947	ETH.MESH.02013948	Zaddem V email chain re Your input on 30 in 3 and Speed to launch
3/25/2010	ETH.MESH.00212665	ETH.MESH.00212665	Draft TVT Family strategic positioning overview presentation
4/6/2010	ETH.MESH.10632641	ETH.MESH.10632644	Elbert K email chain re CO-0022344 for your review; Target Approval 4-12-2010 12:00:00 AM EDT
4/6/2010	ETH.MESH.11205022	ETH.MESH.11205027	Email Katrin Elbert to Sheelu Samuel re FW: CO-0022344 for your review; Target Approval 04-12-2010 12:00:00 AM EDT
4/6/2010	ETH.MESH.14819286	ETH.MESH.14819290	Taggart D email chain re CO-002344 for your review: Target Approval 04-12-2010 12:00 AM EDT
4/6/2010	ETHMESH.CHAHAL.00000006	ETHMESH.CHAHAL.00000027	Chahal Employee Secrecy, Intellectual Property, Non-Competition and Non-Soliciation Agreement
4/7/2010	ETH.MESH.00602025	ETH.MESH.00602027	Robinson D email re Please hold: database study vendor selection

4/9/2010	ETH.MESH.05620358	ETH.MESH.05620362	NCR Summary Report NCR10-01914
4/13/2010	ETH.MESH.09656790	ETH.MESH.09656795	Trzewik J email chain re laser cutting
4/14/2010	ETH.MESH.00223801	ETH.MESH.00223828	TVT Retropublic Refresh
4/19/2010	ETH.MESH.00574783	ETH.MESH.00574783	Waltregny D email chain re Your Submission
4/19/2010	ETH.MESH.03627114	ETH.MESH.03627114	Wess A email chain re de leval paper
4/28/2010	ETH.MESH.00750880	ETH.MESH.00750881	TVT Family of Products Co-positioning EWHU Board Pre-Reading
5/12/2010	ETH.MESH.02340902	ETH.MESH.02340973	TVT-O IFU (-present)
5/14/2010	ETH.MESH.01320395	ETH.MESH.01320519	Biocompatibility Assessment of Medi-Line Use of Down Corning 200 Fluid (100 cst) In Gynecare TVT Products
5/28/2010	ETH.MESH.00493332	ETH.MESH.00493343	Consulting Agreement Requistion Form between Brian J. Flynn and Ethicon
6/14/2010	ETH.MESH.03642659	ETH.MESH.03642659	2011 EWHU Business Planning presentation
6/16/2010	ETH.MESH.05347751	ETH.MESH.05347769	Hart email chain re Investigator-Initiated Studies Policy
6/29/2010			Total Petrochemicals Certificate 10D0649
6/30/2010	ETH.MESH.06869163	ETH.MESH.06869166	Landgrebe email chain re matrix - Cohera
7/5/2010	ETH.MESH.03497846	ETH.MESH.03497847	MD&D Complaint Form - Complaint ID CC1007005
7/5/2010	ETH.MESH.13204508	ETH.MESH.13204521	Email Kathie Chen to Darlene Jane Kyle, et al. re Product Complaint CC1007005-Taiwan
7/6/2010	ETH.MESH.02254165	ETH.MESH.02254165	Beath C email chain re 510K clearance
7/12/2010	ETH.MESH.13896042	ETH.MESH.13896043	Poulot email chain re BHR EWHU 3413118, 398077, 3405428
7/13/2010	ETH.MESH.01675805	ETH.MESH.01675806	Samuel S email re Key Steps Flashcare Clarification
7/15/2010	ETH.MESH.02019485	ETH.MESH.02019485	Email Vincenza Zaddem to Alyssa Kilayko re obt muscle thickness values
8/3/2010	ETH.MESH.14967283	ETH.MESH.14967283	Complaint Number: PI1-F8GCTO
8/3/2010	ETH.MESH.14908783	ETH.MESH.14908783	Complaint Number: PI1-EWT0A6

8/8/2010	ETH.MESH.01201955	ETH.MESH.01201956	Pagel K email re Prof Ed deck (draft 2 still) w/o video
8/11/2010	ETH.MESH.00826028	ETH.MESH.00826045	Hinoul Clinical Expert Report
8/16/2010	ETH.MESH.03432766	ETH.MESH.03432766	Email Brian Flynn to Jonathan Fernandez re permission
8/17/2010	ETH.MESH.13907354	ETH.MESH.13907355	Jaccard email chain re Particles in production w/attacment
8/17/2010	ETH.MESH.13210344	ETH.MESH.13210346	Email Celine Heramza to Carolyn Brennan re Assignment "Product evaluation" has been closed for Issue #:10100122655
8/17/2010	ETH.MESH.03497878	ETH.MESH.03497878	MD&D Resolution Form
8/17/2010	ETH.MESH.01795909	ETH.MESH.01795929	Hinoul Clinical Expert Report
8/24/2010	ETH.MESH.01745568	ETH.MESH.01745572	Email from Carlos E. Lugo-Ponce to Darlene Jane Kyle et al re Product Complaint CC1007005-Taiwan
9/1/2010	ETH.MESH.04101817	ETH.MESH.04101822	Email Shalot Armstrong to Carlos E Lugo-Ponce re Product Complaint CC1007005-Taiwan
9/13/2010	ETH.MESH.03721328	ETH.MESH.03721449	Meier CER Mesh Erosions
9/30/2010	ETH.MESH.08344659	ETH.MESH.08344659	Email Kevin Mahar to Libby Lewis RE: Key docs at AUGS
9/30/2010	ETH.MESH.09218058	ETH.MESH.09218058	Peebles R email re Transcription
11/8/2010	ETH.MESH.10132609	ETH.MESH.10132620	Innovation Council agenda
12/6/2010	ETH.MESH.01226442	ETH.MESH.01226445	Kirkemo A Dear Dr. unsolicated request for information letter
12/6/2010	ETH.MESH.01265511	ETH.MESH.01265511	Kirkemo A email re Your unsolicited request for medical information - MIR
12/9/2010	ETH.MESH.08041930	ETH.MESH.08041931	Irvin email re 12/8 Post Call Notes
12/9/2010	ETH.MESH.06087513	ETH.MESH.06087514	TVTR-566-10-11/12 Physician brochure - Gynecare TVT
12/9/2010	ETH.MESH.05791132	ETH.MESH.05791133	Henderson M email chain re Q4 Spend
1/1/2011	ETHMESH.CHAHAL.00000001	ETHMESH.CHAHAL.00000005	2011 Performance and Development Plan Summary for Chahal

1/20/2011	ETH.MESH.00791766	ETH.MESH.00791813	PowerPoint - Physician Survey Results January 20, 2011
1/22/2011	ETHMESH.CHAHAL.00000052	ETHMESH.CHAHAL.00000063	Lewis L - 2011 Field Visit Letter, Chahal
1/26/2011	ETH.MESH.08003303	ETH.MESH.08003318	Patient Brochure - Treatment Options for Stress Urinary Incontinence -- stop coping. start living.
2/1/2011	ETH.MESH.05276184	ETH.MESH.05276194	Master Consulting Agreement between Dr. Douglas Grier and Ethicon
2/7/2011	ETH.MESH.08003295	ETH.MESH.08003302	TVT-039-11-1/13 Patient brochure - stop coping. start living
2/8/2011	ETH.MESH.06016054	ETH.MESH.06016055	Dang email chain re K103727 - please advise
2/8/2011	ETH.MESH.10630803	ETH.MESH.10630808	Braskem MSDS C4001 Polypropylene
2/14/2011	ETH.MESH.03981288	ETH.MESH.03981290	Roji A email re VOTE team 2010 1:1 calls
2/15/2011	ETH.MESH.05604390	ETH.MESH.05604399	FDA Review of PFR and SUI Mesh Products - Changing Regulatory Environment and Potential Impact on Ethicon Pipeline - presentation
2/16/2011	ETH.MESH.02010834	ETH.MESH.02010855	Biomechanical consideration for Pelvic floor mesh design
2/21/2011	ETHMESH.OHARA.00000347	ETHMESH.OHARA.00000353	Lewis 2010 Performance and Development Plan Summary for O'Hara
2/23/2011	ETH.MESH.02219202	ETH.MESH.02219210	Material Specification for TVT Prolene Polypropylene Mesh Roll Stock, Rev. 5
2/23/2011	ETH.MESH.01216125	ETH.MESH.01216150	Internal Notes - Memo
2/24/2011	ETH.MESH.08005908	ETH.MESH.08005909	Email Jonathan Fernandez to Brian Flynn, et al. re Flynn contracts
2/28/2011	ETH.MESH.00206973	ETH.MESH.00206973	Gauld email re Here is the copy of FDA's letter (please do not forward)
2/28/2011	ETH.MESH.08170224	ETH.MESH.08170232	Kevin Frost email chain re SGS Fellows Symposium
3/7/2011	ETH.MESH.06015196	ETH.MESH.06015196	Benjamin email re FDA ltt re 510k
3/7/2011	ETH.MESH.03898831	ETH.MESH.03898834	Garbarino S email chain re 2011 VOTE Team Conf Call - VOTE Team Questions

3/8/2011	ETH.MESH.00575160	ETH.MESH.00575161	Papas N email chain re AUGS abstract
3/9/2011	ETH.MESH.16434349	ETH.MESH.16434352	Papas N email chain re AUGS Abstract
3/9/2011	ETH.MESH.02592467	ETH.MESH.02592470	Kirkemo A Dear Dr. unsoliciated request for information letter
3/11/2011	ETH.MESH.05276086	ETH.MESH.05276097	Master Consulting Agreement between Brian J. Flynn and Ethicon
3/13/2011			TVT Patient Brochure Chart - TVT/SUI Patient Brochures
3/14/2011	ETH.MESH.05163323	ETH.MESH.05163325	Email Alyson Wess to Georgia Long, et al. re
3/15/2011	ETH.MESH.18846146	ETH.MESH.18846147	Kaminski email chain re Prosima Preparation
3/15/2011	ETH.MESH.12627553	ETH.MESH.12627577	Elaine Wise Product Monograph
3/17/2011	ETH.MESH.04062405	ETH.MESH.04062407	Wess A email chain re Incontinence PMT: 3/3 meeting notes
3/29/2011	ETH.MESH.08969368	ETH.MESH.08969368	Frost K email re PF Summit Presentations
3/31/2011	ETH.MESH.07236294	ETH.MESH.07236295	Hinoul email chain re Workshop on Vaginal Tapes
3/31/2011	ETH.MESH.11790162	ETH.MESH.11790162	Phillips, K email re Lack of quality engineering support for Prosima+M
3/31/2011	ETH.MESH.10818814	ETH.MESH.10818814	EWHU: Faculty Training - Sonoma CA Agenda
4/1/2011	ETH.MESH.10818815	ETH.MESH.10818816	Ethicon 2011 Incontinence & Pelvic Floor Summit agenda
4/19/2011	ETH.MESH.00540629	ETH.MESH.00540629	Monthly Complaint Review
4/21/2011	ETH.MESH.10818812	ETH.MESH.10818813	Frost K email re 2011 Incontinence & Pelvic floor REcap
5/13/2011	ETH.MESH.05822684	ETH.MESH.05822693	Email Laura Hutto to Brian Luscombe re Flynn
5/16/2011	ETH.MESH.03643726	ETH.MESH.03643726	US EWHU Executive Performance Review Presentation
5/18/2011	ETH.MESH.02589032	ETH.MESH.02589079	PA Consulting Group Report: Investigating Mesh Erosion in Pelvic Floor Repair
5/18/2011	ETH.MESH.03750903	ETH.MESH.03750950	Berman, Robinson, Wang, Rhodes - Report - Investigating Mesh Erosion in Pelvic Floor Repair

6/22/2011	ETH.MESH.07192929	ETH.MESH.07192929	Investigating Mesh erosion in Pelvic Floor Repair - Report Bernman, Robinson, Wang Rhodes - presentation
6/30/2011	ETH.MESH.07903682	ETH.MESH.07903683	Affeld, T email chain re PS vs +M
7/6/2011	ETH.MESH.05337217	ETH.MESH.05337220	Miller D email chain re Prolift professional education
7/6/2011	ETH.MESH.05337225	ETH.MESH.05337228	Luscombe B email chain re request from Miller re lecture material
7/13/2011	N/A	N/A	FDA Public Health Notification
7/13/2011	ETH.MESH.02253078	ETH.MESH.02253079	Email Bridget Ross (WW President, EWH&U) re FDA Health Notification
7/20/2011			Letter Dr. David Challoner to Dr. Jeffrey E. Shuren re seven recommendations proposed by FDA
7/22/2011	ETH.MESH.17556556	ETH.MESH.17556556	Chahal R email chain re Umaima Jamaluddin procedure questions
7/29/2011	ETH.MESH.00301367	ETH.MESH.00301369	Email Vijay Madikonda re BSI Technical File Audit - July 28-29, 2011
8/26/2011	ETH.MESH.06261965	ETH.MESH.06261967	Karl J email chain re Braskem. . . A LIttle History
8/30/2011	ETH.MESH.11175841	ETH.MESH.11175842	Samuel S email re Mesh Data
9/30/2011			FDA - Considerations about Surgical Mesh for SUI
10/6/2011	ETH.MESH.11445493	ETH.MESH.11445494	Email LIbby Lewis to Mary Byerly re Western Region Needs
12/6/2011	ETH.MESH.09977270	ETH.MESH.09977271	PLT 12 month post-launch close out PPT - slide 17 Executive Summary.
1/30/2012	ETHMESH.OHARA.00000354	ETHMESH.OHARA.00000359	O'Hara 2011 Performance and Development Plan Summary - Libby Lewis
2/1/2012	ETH.MESH.09155883	ETH.MESH.09155895	Grier Consulting Agreement Requisition Form
2/1/2012	ETH.MESH.09155909	ETH.MESH.09155920	Consulting Agreement Requisition Form - Part I Ethicon and Melvyn A. Anhalt

2/6/2012	ETH.MESH.17556591	ETH.MESH.17556593	Chahal R email re Booking Confirmation Jeremy William Aaron - Phoenix, Feb 13
2/16/2012	ETH.MESH.03644217	ETH.MESH.03644217	PowerPoint - EWHU Incontinence 2012 Pipeline Refresh
2/24/2012	ETH.MESH.07730291	ETH.MESH.07730295	Lapinskas, I, email chain originating re Discussion of 3.5 mil Prolene production
3/1/2012	ETH.MESH.07226377	ETH.MESH.07226379	Vellucci, L email chain re Polypropylene Mesh
3/1/2012	ETH.MESH.04015102	ETH.MESH.04015104	Batke B email chain re AGES Pelvic Floor Conference - Gala Dinner Invitation
3/3/2012	ETHMESH.OHARA.00000313	ETHMESH.OHARA.00000314	O'Hara Employee Profile
3/6/2012	ETH.MESH.07455220	ETH.MESH.07455221	Response to MHRA inquiry regarding inertness of polypropylene mesh
3/7/2012	ETH.MESH.02652179	ETH.MESH.02652317	Issues Report Run Between and
3/12/2012	ETH.MESH.07205369	ETH.MESH.07205370	Savidge, et al response to email from Huntington re Clave' publication
3/12/2012	ETH.MESH.05998775	ETH.MESH.05998778	Hinoul P email chain re Patient complication in Wichita, KS
3/14/2012	ETH.MESH.07724068	ETH.MESH.07724080	Independent MD&D Sector Audit by QualityHub, Inc. Pore size
3/15/2012	ETH.MESH.04037600	ETH.MESH.04037600	Innovations in Mesh Development by Boris Batke
3/25/2012	ETH.MESH.13681529	ETH.MESH.13681532	The efficacy she needs with less mesh
4/2/2012	ETH.MESH.17556496	ETH.MESH.17556497	Barnes C email chain re Ethicon Gynecare Innovations Event
4/3/2012	ETH.MESH.17556511	ETH.MESH.17556511	Barnes C email chain re ACT REQ: Urgent quick need request
4/3/2012	ETH.MESH.17556598	ETH.MESH.17556598	Chahal R email chain re ACT REQ Urgent quick need
4/4/2012	ETH.MESH.17556512	ETH.MESH.17556512	Langen B email re SMII Welcome Letter
4/5/2012	ETH.MESH.17556486	ETH.MESH.17556487	Luscombe B email re Brand Team for Inc POP
4/12/2012	ETH.MESH.17556513	ETH.MESH.17556513	Langen B letter re Sales Mastery II
4/12/2012	ETH.MESH.17556498	ETH.MESH.17556498	Ethicon Gynecare Innovations flyer

4/27/2012	ETH.MESH.05572526	ETH.MESH.05572528	Hinoul P email chain re slings at surgery center
5/1/2012	ETH.MESH.08066401	ETH.MESH.08066414	Pramudji fax re Contract
5/15/2012	ETH.MESH.08065931	ETH.MESH.08065943	Master Consulting Agreement between Melvyn A. Anhalt and Ethicon
5/18/2012	ETHMESH.CHAHAL.00000051	ETHMESH.CHAHAL.00000051	Chahal Employee Profile
6/14/2012	ETH.MESH.05815791	ETH.MESH.05815802	TVT-172-12-6/14 Patient Brochure - Stop Coping. START LIVING. WHAT YOU SHOULD KNOW ABOUT STRESS URINARY INCONTINENCE
6/16/2012	ETH.MESH.09158424	ETH.MESH.09158430	ARTISYN Advisory Board notes
7/26/2012	ETH.MESH.05125293	ETH.MESH.05125297	Email Piet Hinoul to Axel Arnaud re article "The perils of commercially driven surgical innovation"
8/6/2012	ETH.MESH.13376756	ETH.MESH.13376758	Work Instructions for In-Process & Finished Goods Defect Classifications for Ethicon Products, Appendix 8 - Mesh
8/6/2012	ETH.MESH.13376759	ETH.MESH.13376768	Primary Blister Defect Definitions and Classifications Release Level: 4. Production
8/7/2012	ETH.MESH.09478633	ETH.MESH.09478636	Chen email chain re New Complaint Form 23125
8/7/2012	ETH.MESH.11529265	ETH.MESH.11529266	Doyle email chain re Surgeon request for follow up 10100175641
8/20/2012	ETH.MESH.09478684	ETH.MESH.09478688	Chen M email chain re Urgent - MDR serious injuries Gynecare France
1/6/2013	ETH.MESH.03685918	ETH.MESH.03685925	Amin D Gynecare Protfolio Presentation
1/11/2013	ETH.MESH.13374555	ETH.MESH.13374558	Chung email chain re Gynecare RFP
1/21/2013	ETH.MESH.14348386	ETH.MESH.14348388	Tait email chain re Non conform lids
2/15/2013	ETH.MESH.13274846	ETH.MESH.13274847	Connaughton email chain re New litigation Prolift & TVT
2/15/2013	ETH.MESH.13274855	ETH.MESH.13274856	Connaughton email chain re new litigation Prolift & TVT
3/11/2013			Hellhammer_091113_04 - Designation Run Report

3/20/2013	ETH.MESH.13208194	ETH.MESH.13208196	Connaughton email chain re New ligitation TVT
3/20/2013	ETH.MESH.10633520	ETH.MESH.10633528	Revision History of MS-0000108
3/26/2013	ETH.MESH.08073801	ETH.MESH.08073803	Rahman communication - AUGS Issues Statement Opposing the Restriction of Surgical Options for Pelvic Floor Disorders
4/25/2013	ETH.MESH.02342194	ETH.MESH.02342194	IFU Index and Production Bates Range Chart
5/3/2013	ETH.MESH.09744870	ETH.MESH.09744871	TVT 20130503
5/3/2013	ETH.MESH.10287104	ETH.MESH.10287439	Hinoul CER Gynecare TVT Family of Products
5/8/2013	ETH.MESH.09909830	ETH.MESH.09909882	Biocompatibility Risk Assessment Report for Gynecare TVT Product Family
5/23/2013	ETH.MESH.13259844	ETH.MESH.13259845	Connaughton email chain re New litigation
5/24/2013	N/A	N/A	IFU__in_Use__Production_Chart
6/5/2013	ETH.MESH.14852591	ETH.MESH.14852592	McNelis email re new litigation TVT & Prosima
6/5/2013	ETH.MESH.14901756	ETH.MESH.14901757	McNelis email re new litigation TVT & Prosima
6/19/2013	ETH.MESH.09732998	ETH.MESH.09733718	Issue Reports Open Date BEtween 01-Jan-2005 and 02-Jun-2013
6/21/2013	ETH.MESH.12910023	ETH.MESH.12910026	Weisberg email chain re TVT mesh elongation FW: dr. Kenny Maslow
6/21/2013	ETH.MESH.12910030	ETH.MESH.12910032	Weisbert email chain re TVT mesn elongation FW: Dr. Kenny Maslow
6/25/2013	ETH.MESH.12910111	ETH.MESH.12910113	Weisberg email chain re TVT mesh enlongation - Redacted
6/27/2013	ETH.MESH.08315779	ETH.MESH.08315810	Ex T-722 MItchell - Clinical Expert Report Gynecare Prolift +M
7/19/2013	ETH.MESH.10150515	ETH.MESH.10150849	Clinical Evaluation Report Gynecare TVT Family of Products
8/5/2013	ETH.MESH.12877116	ETH.MESH.12877117	Amin email chain re HPG Pelvic Floor RFP
8/19/2013	ETH.MESH.13292806	ETH.MESH.13292807	Finch email chain re New litigation TVT-S
8/26/2013	N/A	N/A	TVT Patient Brochure Index 8-26-13
8/28/2013	ETH.MESH.12913351	ETH.MESH.12913356	Hinoul email re MIR TVT - ilioninguinal pain w/attachment

9/12/2013			Hellhammer_091213_03 - Designation Run Report
9/17/2013	ETH.MESH.12906504	ETH.MESH.12906506	Librojo email chain re Copy Review Exception
9/21/2013	ETH.MESH.13296239	ETH.MESH.13296240	Gallo email chain re new litigation TVT
9/30/2013	ETH.MESH.10591939	ETH.MESH.10591949	Angelini Browse JJEDS Object Detail form
11/7/2013	ETH.MESH.15034561	ETH.MESH.15034562	McNelis email new litigation TVT
11/7/2013	ETH.MESH.12907174	ETH.MESH.12907174	Jacobs email chain re defect to harms map
11/9/2013	ETH.MESH.14896228	ETH.MESH.14896229	Finch email re new litigation TVT
1/3/2014			AUGS Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence
1/6/2014	ETH.MESH.14852593	ETH.MESH.14852595	Killins email chain re Addtl info - new litigation TVT & Prosima
1/6/2014	ETH.MESH.14901758	ETH.MESH.14901760	Killins email chain re Addtl info new litigation TVT & Prosima
1/9/2014	ETH.MESH.17640736	ETH.MESH.17640767	Corrado email re QRB presentation
1/30/2014	ETH.MESH.14994657	ETH.MESH.14994659	Tran email chain re Addtl Info -
1/31/2014	ETH.MESH.14967286	ETH.MESH.14967287	Jackson email chain Addtl Info -
2/4/2014	N/A	N/A	United States Patent De Leval US8641597
2/4/2014	ETH.MESH.14896230	ETH.MESH.14896232	Piper email chain re Addtl info
2/5/2014			Exhibit T-3604 LCM sales inside the US
2/6/2014	ETH.MESH.16357097	ETH.MESH.16357097	Sedlatschek email chain re Secant Medical Inquiry on Gynecare Mesh Products
2/7/2014	ETH.MESH.17777763	ETH.MESH.17777768	Sedlatschek email re Secant Medical Inquiry on Gynecare Mesh Products
2/7/2014	ETH.MESH.14896233	ETH.MESH.14896235	Tran email chain re addtl info 1/30/14
3/26/2014	HMESH_ETH_06033196	HMESH_ETH_06033202	Rodriguez email chain re Nilsson 2013
3/27/2014	ETH.MESH.17619399	ETH.MESH.17619405	Rodriguez email chain re Secant Medical Inquiry on Gynecare Mesh Products
4/14/2014	ETH.MESH.17642669	ETH.MESH.17642686	PQI Revision 10
5/2/2014	ETHMESH.OHARA.00000360	ETHMESH.OHARA.00000362	O'Hara Career Development Profile

5/19/2014	ETH.MESH.17777759	ETH.MESH.17777762	Rodiguez email chain re UPDATE to Escalation Notice - Section 39 Request - TVT, Gynemesh PS & Artisyn Y-Shared Mesh
6/9/2014			Total Units Sold Chart - Product data
6/20/2014			Letter Dr. Aileen Keel to Colleague re Transvaginal mesh implants
6/28/2014			Management of Mesh Complications AUGS and IUGA 2014 CButrick
7/17/2014	ETHMESH.CHAHAL.00000049	ETHMESH.CHAHAL.00000050	Chahal Career Development Profile
12/2/2014			About Banque Carnegie Luxembourg - HL - Banque Carnegie Luxembourg
2/2/2015			tvt lightweight Google search
2/17/2015	ETH.MESH.03625982	ETH.MESH.03625982	List of Preceptor Names and Events Attended
2002	ETH.MESH.00340836	ETH.MESH.00340838	CER Update for TVT
2002			ASTM D 1388-96 - Standard Test Method for Stiffness of Fabrics
2003	HMESH_ETH.07269753	HMESH_ETH.07269765	Contact Points - Nummular allergic contact dermatitis after scabies treatment, R. Kaminska, et al
2003			T 437 om -03 Dirt in Paper and Paperboard
2006			AMS Solutions for Life Preserving Mesh Integrity, Simplifying Tensioning
2006	ETH.MESH.00746209	ETH.MESH.00746209	Product Pointer
2007	ETH.MESH.08003247	ETH.MESH.08003262	TVT 20070531 Patient Brochure - The Choice to End Stress Urinary Incontinence Find out how to stop urine leakage like Bonnie did
2007	ETH.MESH.06861946	ETH.MESH.06861946	Basell Purell MSDS
2007	ETH.MESH.00163582	ETH.MESH.00163597	Brochure "Find out how to stop urine leakage like Bonnie did"
2008	ETH.MESH.07474296	ETH.MESH.07474407	ANSI/AAMI/ISO 10993-7:2008

2008	ETH.MESH.00658453	ETH.MESH.00658458	Brochure The Gynecare TVT Family of Products 3 SUI Solutions. Delivering Data, Safety & Choice.
2009	ETH.MESH.00002162	ETH.MESH.00002177	Stop coping. Start living
2010	ETH.MESH.00499024	ETH.MESH.00499024	2010 preceptor payments spreadsheet
2010	ETH.MESH.00346194	ETH.MESH.00346201	The efficacy she needs with less mesh - annotated - round 3
2010	ETH.MESH.06260647	ETH.MESH.06260671	R&D CO-OP Welcome Guide Spring 2010
2010	ETH.MESH.02236784	ETH.MESH.02236785	Physician patient follow-up form letter
2011	ETH.MESH.00790545	ETH.MESH.00790546	Competitive Dissection Flashcard
2011	ETH.MESH.14273633	ETH.MESH.14273668	Ethicon Neuchâtel A changing Product Protfolio
2011	ETH.MESH.08078799	ETH.MESH.08078799	TVT-US
2011	ETHMESH.CHAHAL.00000044	ETHMESH.CHAHAL.00000048	ChahalHospital Sales Spreadsheet
2011	ETH.MESH.04005863	ETH.MESH.04006038	Ozog, Yves Doctorial Thesis: Theoretical and Experimental Evaluation of Implant Materials Used in Pelvic Organ Prolapse Repair
2011	ETH.MESH.17556578	ETH.MESH.17556579	2011 Price List
2012	ETH.MESH.09744848	ETH.MESH.09744855	TVT-312-12 Patient Brochure - stop coping. start living. GYNECARE TVT Family of Products
2012	ETH.MESH.07808484	ETH.MESH.07808486	Frequently Asked Questions Clinical Data Review 3-Year Data Flashcard
2013	ETH.MESH.16308087	ETH.MESH.16308090	Patient Brochure
2013	ETH.MESH.09744840	ETH.MESH.09744845	TVT-131-13 Patient Brochure - stop coping start living. What You Should Not About Stress Urinary Incontinence
2013			AUA 2013 Annual Meeting Highlights Voiding Dysfunction/Female Urology
2014	T-1499	T-1499	Total Units Sold Chart
2014			Webpage "A Solution: Gynecare TVT Tension-free Support for Incontinence"
1/2002	ETH.MESH.08793554	ETH.MESH.08793554	DTC Advertising Patient Potential January 2002 Presentation

1/2010	ETH.MESH.03643186	ETH.MESH.03643186	Ethicon Women's Health and Urology Brand Equity Study Final Report
2/2002	ETH.MESH.00339437	ETH.MESH.00339442	5 Years of Proven Performance TVT Sales Aid (TVT041)
3/2011	ETH.MESH.05479717	ETH.MESH.05479717	ETHICON Polypropylene Mesh Technology- Batke presentation
4/2008	ETH.MESH.00006636	ETH.MESH.00006636	Klosterhalfen Interim report mesh explants pelvic floor repair
6/2000	ETH.MESH.00400957	ETH.MESH.00400978	TVT Surgeons Resource Monograph
6/2003			Clark Urological Center Newsletter
7/2002	ETHMESH.OHARA.00000304	ETHMESH.OHARA.00000312	O'Hara Application for Employment
7/2009	ETH.MESH.05764101	ETH.MESH.05764101	BUC July 2009 I&pf platforms presentation
7/2013			ICS Fact Sheets A Background to Urinary and Faecal Incontinence prepared by the Publications & Communications Committee, July 2013
8/2009	ETH.MESH.00533025	ETH.MESH.00533026	HS Study Monthly Update
8/2010	ETH.MESH.03422160	ETH.MESH.03422162	Clinical Data Review Presented at ICS/IUGA Aug 2010
9/2004	ETH.MESH.03571983	ETH.MESH.03572098	Physician Segmentation Study for Gynecare TVT Final Presentation - Copernieus
9/2007	HMESH_ETH_00660369	HMESH_ETH_0066078	Pleiger - Polyamid.nylon MSDS
9/2010	ETH.MESH.09932902	ETH.MESH.09932912	Neuchatel - September 2010 Roles and Responsibilities
9/2010	ETH.MESH.09932908	ETH.MESH.09932918	Neuchatel - September 2010 Roles and Responsibilities
10/2000	ETH.MESH.04044797	ETH.MESH.04044800	TVT Update Success & Complications - Bernard Jacquetin
10/2008	ETH.MESH.17556582	ETH.MESH.17556582	IFPM position on FDA notification
10/2011			AUA HP Brief - Billing for Sling Revisions and Urethrolysis

10/2012	ETH.MESH.07808480	ETH.MESH.07808481	The efficacy she need with less mesh. Clinical Data Review - 3 Year Data
	ETH.MESH.08426862	ETH.MESH.08426867	Toglia Presentation - The Mesh Story working copy
	HMESH_ETH_06509816	HMESH_ETH_06509816	Text File
			Study Slides - various testimony
			Jordi SEM and OM Images
			Chart of Responsive Documents
	ETH.MESH.11175843	ETH.MESH.11175843	The Science of "What's Lift Behind" . . . presentation
	ETH.MESH.01592467	ETH.MESH.01592490	Test Method Validation Protocol: Visual Acceptance criteria for seal of Blister PVA-112940-TMV-PR
	ETH.MESH.09214439	ETH.MESH.09214439	Toglia, The Mesh Story presentation
	ETH.MESH.04941016	ETH.MESH.04941049	Holste presentation: Lightweight Mesh Developments
	ETH.MESH.14901753	ETH.MESH.14901753	Complaint PI1E8VOWN
	ETH.MESH.15406916	ETH.MESH.15406919	Guidoin Lab Notebook Page/Image
	ETH.MESH.13797826	ETH.MESH.13797830	Check Liste D'Inspection QUalite
	ETH.MESH.13376661	ETH.MESH.13376868	Draft Template: DRM for Device Functionality (Performance & Safety)
	ETH.MESH.00301977	ETH.MESH.00301977	TVT Laser Cut Mesh Project Revision History for DFMEA0000242
	ETH.MESH.09671620	ETH.MESH.09671620	Material specification spreadsheet
	ETH.MESH.00632655	ETH.MESH.00632655	U.S. Launch Overview
			CV of Piet Hinoul
	ETH.MESH.15958470	ETH.MESH.15958477	Guidoin Lab Notebook Page/Image
	ETH.MESH.00355435	ETH.MESH.00355435	Differentiation Statement
	ETH.MESH.11175844	ETH.MESH.11175844	TVT Complication comparison matrix
	ETH.MESH.00074499	ETH.MESH.00074499	Presentation: Gynecare Prolift+M Pelvic Floor Repair System Training

	ETH.MESH.02106741	ETH.MESH.02106743	Surgeon Evaluation Questions for Laser Cut Mesh
	ETH.MESH.00271641	ETH.MESH.00271641	Franco presentation - The Science of "What's Left Behind" . . . Evidence & Follow-Up of Mesh Use for SUI
	ETH.MESH.15406979	ETH.MESH.15406981	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406920	ETH.MESH.15406921	Guidoin Lab Notebook Page/Image
	ETH.MESH.08334245	ETH.MESH.08334245	LCM Project: Photographs Comparing Laser Cut Mesh vs Mechanical Cut Mesh
	ETH.MESH.15406956	ETH.MESH.15406957	Guidoin Lab Notebook Page/Image
	ETH.MESH.02108293	ETH.MESH.02108295	Division Meeting Notes: Continence Health
	ETH.MESH.00223800	ETH.MESH.00223800	Powerpoint TVT Retropublic Refresh
	ETH.MESH.14471186	ETH.MESH.14471186	Spreadsheet
	ETH.MESH.08968369	ETH.MESH.08968378	Ailawadi - Does Material Matter - final
	ETH.MESH.01310061	ETH.MESH.01310065	TVT Laser Cut RMR Rev 2
	ETH.MESH.02236580	ETH.MESH.02236595	Patient Brochure - Stop coping. Start Living. Gynecare TVT Family of Products
	ETH.MESH.00581483	ETH.MESH.00581486	Gynecare International Convention Recommendations
	ETH.MESH.03738466	ETH.MESH.03738467	Emails Martin Weisberg and Dr Peggy Norton re TVT
	ETH.MESH.07506983	ETH.MESH.07506985	Biocompatibility Risk Assessment: PROSIMA Pelvic Floor Repair System (Mint)
	ETH.MESH.06866921	ETH.MESH.06866921	ETH.MESH.06866921 attachment
	ETH.MESH.15406942	ETH.MESH.15406943	Guidoin Lab Notebook Page/Image
			Grier with notes T-752
	ETH.MESH.15406958	ETH.MESH.15406960	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406971	ETH.MESH.15406971	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406977	ETH.MESH.15406977	Guidoin Lab Notebook Page/Image
	ETH.MESH.01066916	ETH.MESH.01066932	TVT and TVT-O RMR Rev 1
	ETH.MESH.15406976	ETH.MESH.15406976	Guidoin Lab Notebook Page/Image
	ETH.MESH.13374559	ETH.MESH.13374559	RFI Instructions

	ETH.MESH.05644163	ETH.MESH.05644171	Pelvic Floor Repair -- Surgeon's Feed-back on Mesh Concept
	T-3137	T-3137	Material Safety Data Sheet, Chevron Philips 2004
	ETH.MESH.03730703	ETH.MESH.03730722	Check Liste D'Inspection Qualite - Final TVT-TVT-AA
	ETH.MESH.04321413	ETH.MESH.04321417	Check Liste D'Inspection Qualite
	ETH.MESH.15406906	ETH.MESH.15406909	Guidoin Lab Notebook Page/Image
	ETH.MESH.04077109	ETH.MESH.04077145	Grier Presentation - The Science of "What's Left Behind" . . . Evidence & Follow-Up of Mesh Use for SUI
			Copy of IFU__in_Use__Production_Chart
	ETH.MESH.01310482	ETH.MESH.01310482	Spreadsheet DFMEA's TVT Classic
			Gynecare_Professional_Education_Digital_Library
	ETHMESH.CHAHAL.00000028	ETHMESH.CHAHAL.00000048	Chahal sales spreadsheets
			Degradation Slides
	ETH.MESH.00353476	ETH.MESH.00353476	Annotated Slide
	ETH.MESH.05442973	ETH.MESH.05442975	Applied Science & Technology Performance Evaluation Abstract Biaxial testing of two commonly used Ethicon meshes
	ETH.MESH.15406846	ETH.MESH.15406856	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406929	ETH.MESH.15406930	Guidoin Lab Notebook Page/Image
	ETH.MESH.00223634	ETH.MESH.00223655	DHF0000747 TVT Retropublic Refresh
	ETH.MESH.00589494	ETH.MESH.00589494	Spreadsheet DFMEA's TVT Classic
	ETH.MESH.04081871	ETH.MESH.04081872	Chen, Medical Assessment - . . . 68 issues from Germany
	ETH.MESH.01226446	ETH.MESH.01226449	Dr. Letter
	ETH.MESH.15406944	ETH.MESH.15406945	Guidoin Lab Notebook Page/Image
			Design FMEA: TVT Laser Cut Mesh Project spreadsheet
	ETH.MESH.03932912	ETH.MESH.03932914	The history of TVT

	ETH-50330	ETH-50330	Slide: Selecting the Right Mesh
	ETH.MESH.15406954	ETH.MESH.15406955	Guidoin Lab Notebook Page/Image
	ETH.MESH.11175864	ETH.MESH.11175864	Gynecare TVT Exact Gynecare TVT Tension-free Support for Incontinence Clinical Data Presentation
	ETH.MESH.03751168	ETH.MESH.03751168	Table comparing meshes
	ETH.MESH.15406975	ETH.MESH.15406975	Guidoin Lab Notebook Page/Image
	HMESH_ETH_02781707	HMESH_ETH_02781708	Stockholm Trip Report
	ETH.MESH.00826046	ETH.MESH.00826047	Product Complaints Graph
	ETH.MESH.03924530	ETH.MESH.03924539	2.0 Products in Development
	ETH.MESH.15406924	ETH.MESH.15406926	Guidoin Lab Notebook Page/Image
			Flexibility/Compliance
	ETH.MESH.04321418	ETH.MESH.04321435	Check Liste D'Inspection Qualite
	ETH.MESH.02249435	ETH.MESH.02249435	New Product Introduction Presentation
	ETH.MESH.02342102	ETH.MESH.02342102	Prolene
	N/A	N/A	Chart of Responsive Documents
	ETH.MESH.00858252	ETH.MESH.00858253	London Brown Memo to Smith re Mechanical Cut vs Laser Cut Mesh Rationale
	ETH.MESH.15406987	ETH.MESH.15406988	Guidoin Lab Notebook Page/Image
	ETH.MESH.01752532	ETH.MESH.01752535	Trzewik - Mesh design argumentation issues
	ETH.MESH.15406893	ETH.MESH.15406894	Guidoin Lab Notebook Page/Image
	ETH.MESH.02237665	ETH.MESH.02237696	Spanish Gynecare TVT patient brochure
	ETH.MESH.02182839	ETH.MESH.02182844	Completion Report, Design Verificaiton for Soft PROLENE Mesh/Mesh Curling
	ETH.MESH.15406998	ETH.MESH.15406999	Guidoin Lab Notebook Page/Image
	ETH.MESH.00748275	ETH.MESH.00748275	Spreadsheet DFMEA's TVT Classic
	ETH.MESH.00223640	ETH.MESH.00223640	Spreadsheet TVT Retropublic Refresh
	ETH.MESH.01310476	ETH.MESH.01310481	TVT RMR Rev 3
	PM.00003.m4v	PM.00003.m4v	Training Videos
	ETH.MESH.06171801	ETH.MESH.06171801	Spreadsheet
	ETH.MESH.15406897	ETH.MESH.15406899	Guidoin Lab Notebook Page/Image

	ETH.MESH.09905193	ETH.MESH.09905193	Survey Results
	ETH.MESH.08505071	ETH.MESH.08505071	Cecchini TVT package insert comments
	ETH.MESH.05119622	ETH.MESH.05119631	Commonly Asked Questions and Objections script
	ETH.MESH.15406961	ETH.MESH.15406962	Guidoin Lab Notebook Page/Image
	ETH.MESH.03905968	ETH.MESH.03905975	Gynecare Pro-lift Ad "Get the Facts, Be Informed, Make YOUR Best Decision"
	ETH.MESH.17556583	ETH.MESH.17556583	Physician Consultation Visit Regarding Decision for Surgery Form
	ETH.MESH.15958510	ETH.MESH.15958511	Guidoin Lab Notebook Page/Image
	ETH.MESH.09004555	ETH.MESH.09004555	Elongation test data - delayed launch
	ETH.MESH.13860322	ETH.MESH.13860342	Check Liste D'Inspection Qualite
			AUGS-SUFU Position Statement drafts
	ETH.MESH.00161444	ETH.MESH.00161445	TVT Detail Sheet (TVTOO1R
	ETH.MESH.15406990	ETH.MESH.15406991	Guidoin Lab Notebook Page/Image
	ETH.MESH.09004554	ETH.MESH.09004554	Elongation test data
	ETH.MESH.08792102	ETH.MESH.08792106	Risk Management Report TVT Laser Cut Mesh (LCM) Revision History for (RMR-000017) Revision 2
	ETH.MESH.01419741	ETH.MESH.01419741	Spreadsheet DFMEA's TVT Classic
	ETH.MESH.04321436	ETH.MESH.04321453	Check Liste D'Inspection Qualite
	ETH.MESH.15406871	ETH.MESH.15406873	Guidoin Lab Notebook Page/Image
	ETH.MESH.02106803	ETH.MESH.02106803	Physician Post-Operative Questionnaire
	ETH.MESH.01250962	ETH.MESH.01250962	Spreadsheet DFMEA's TVT Classic
	ETH.MESH.15406939	ETH.MESH.15406941	Guidoin Lab Notebook Page/Image
	ETH.MESH.00143842	ETH.MESH.00143842	Presentation draft - Tension-Free Support for Female SUI (258 Patients) - Modarelli, et al
	ETH.MESH.15958486	ETH.MESH.15958491	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406884	ETH.MESH.15406885	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406937	ETH.MESH.15406938	Guidoin Lab Notebook Page/Image
	ETH.MESH.05120364	ETH.MESH.05120365	Mesh vs Non-Mesn Pending PR/Regulatory Issues
			510(k) Submission and Communications for TVT Exact

	ETH.MESH.15406963	ETH.MESH.15406964	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406903	ETH.MESH.15406905	Guidoin Lab Notebook Page/Image
	ETH.MESH.08664680	ETH.MESH.08664686	Franchise Procedure for Controlling Substances of Concern Revision History PR-0000558
	ETH.MESH.15406860	ETH.MESH.15406861	Guidoin Lab Notebook Page/Image
	ETH-53294	ETH-53294	Check Liste D'Inspection Qualite
	ETH.MESH.05237034	ETH.MESH.05237037	Trzewik memo re Mesh design argumentation issues
	ETH.MESH.04082973	ETH.MESH.04082974	Study Notes, Meng Chen, PhD, Possible Complications for Surgeries to Correct Pelvic Organ Prolapse
	ETH.MESH.09748848	ETH.MESH.09748853	Consultancy Agreement
	ETH.MESH.15406888	ETH.MESH.15406889	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406877	ETH.MESH.15406879	Guidoin Lab Notebook Page/Image
	ETH.MESH.15958492	ETH.MESH.15958494	Guidoin Lab Notebook Page/Image
	ETH.MESH.15958495	ETH.MESH.15958502	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406948	ETH.MESH.15406949	Guidoin Lab Notebook Page/Image
	ETH.MESH.09293114	ETH.MESH.09293114	Notes re customers frustration with Ethicon rep
	ETH.MESH.08581280	ETH.MESH.08581282	Equivalence Supported by Pre-clinical Performance Studies
	ETH.MESH.09748842	ETH.MESH.09748846	Consultancy Agreement
	ETH.MESH.15958481	ETH.MESH.15958485	Guidoin Lab Notebook Page/Image
	ETH.MESH.00340835	ETH.MESH.00340835	Spreadsheet DFMEA's TVT Classic
	ETH.MESH.15406864	ETH.MESH.15406866	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406869	ETH.MESH.15406870	Guidoin Lab Notebook Page/Image
	ETH.MESH.15958478	ETH.MESH.15958480	Guidoin Lab Notebook Page/Image
	ETH.MESH.00010743	ETH.MESH.00010743	Letter of Proffer: Madigan Army Medical Center
	ETH.MESH.15958512	ETH.MESH.15958517	Guidoin Lab Notebook Page/Image
	ETH.MESH.00301741	ETH.MESH.00301742	Lamont email chain re !!!!Great News for TVT Laser Cut Mesh!!!!
	ETH.MESH.05240144	ETH.MESH.05240144	Article on pp change in sheep model
	ETH.MESH.15406950	ETH.MESH.15406951	Guidoin Lab Notebook Page/Image

	ETH.MESH.15406989	ETH.MESH.15406989	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406874	ETH.MESH.15406876	Guidoin Lab Notebook Page/Image
	ETH.MESH.03906527	ETH.MESH.03906527	Graft or No Graft - Arnaud presentation
			TVT Retropubic Mechanical Cut, US Sales
	ETH.MESH.15406992	ETH.MESH.15406993	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406969	ETH.MESH.15406970	Guidoin Lab Notebook Page/Image
	ETH.MESH.01247379	ETH.MESH.01247379	Spreadsheet DFMEA's TVT Classic
	ETH.MESH.04321405	ETH.MESH.04321408	Check Liste D'Inspection Qualite
	ETH.MESH.08696085	ETH.MESH.08696134	Medscand Agreement Files
	ETH.MESH.08776231	ETH.MESH.08776238	Instruction Standard TVT EXACT product Plan and Rationald Appendix I, Revision A
	ETH.MESH.01218099	ETH.MESH.01218103	TVT Laser Cut Mesh Rev 1
	ETH.MESH.01218019	ETH.MESH.01218019	Revision History for dFMEA0000242
	N/A	N/A	Trial Testimony of Piet Hinoul in Linda Gross Trial
	ETH.MESH.00321804	ETH.MESH.00321805	Definition for Major Invasive Surgeries and The Ethicon Franchise Products Requiring Major Invasive Procedures for Implantation
	ETH.MESH.03671138	ETH.MESH.03671147	MS455-012; Revision 18 Material Specification for Pelletized Unpigmented
	ETH.MESH.15406952	ETH.MESH.15406953	Guidoin Lab Notebook Page/Image
	ETH.MESH.00746210	ETH.MESH.00746212	Surgeon Evaluation Questions for Laser Cut Mesh
	N/A	N/A	Trial Testimony of Melvyn Anhalt, MD in the Linda Batiste Trial
	ETH.MESH.00862284	ETH.MESH.00862289	MS729-XXX;Appendix 1
	ETH.MESH.06195201	ETH.MESH.06195205	Divilio memo
	ETH.MESH.04321454	ETH.MESH.04321471	Check Liste D-Inspection Qualite
	ETH.MESH.15406900	ETH.MESH.15406902	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406985	ETH.MESH.15406986	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406867	ETH.MESH.15406868	Guidoin Lab Notebook Page/Image
	ETH.MESH.14221357	ETH.MESH.14221357	Spreadsheet
	ETH.MESH.15406862	ETH.MESH.15406863	Guidoin Lab Notebook Page/Image

	ETH.MESH.15406972	ETH.MESH.15406972	Guidoin Lab Notebook Page/Image
	ETH.MESH.11917445	ETH.MESH.11917450	TVT Family of Products Sales Rep Promotion TVT Fast Break
	ETH.MESH.13869615	ETH.MESH.13869634	Check Liste D'Inspection Qualite Final TVT/TVT-AA
	ETH.MESH.05479535	ETH.MESH.05479535	Mesh porosity chart
	ETH.MESH.00159634	ETH.MESH.00159719	Toth Memo w/ Gynecare TVT Professional Education Slides
	ETH.MESH.01250926	ETH.MESH.01250926	Spreadsheet DFMEA's TVT Classic
	ETH.MESH.15406967	ETH.MESH.15406968	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406927	ETH.MESH.15406928	Guidoin Lab Notebook Page/Image
			TVT product sales
	ETH.MESH.00528636	ETH.MESH.00528641	Product Quality Plan for Gynecare Gynemesh XL
	ETH.MESH.15406890	ETH.MESH.15406892	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406895	ETH.MESH.15406896	Guidoin Lab Notebook Page/Image
	ETH.MESH.02265803	ETH.MESH.02265809	Spreadsheet DFMEA's TVT Classic
	ETH.MESH.00858080	ETH.MESH.00858081	Smith D Memo re Gynecare Board risk discussion before launch
			Vypro Mesh - Prolene Mesh
	ETH.MESH.15406965	ETH.MESH.15406966	Guidoin Lab Notebook Page/Image
	ETH.MESH.10181793	ETH.MESH.10181797	Ulmsten - Anesthesiological routines for the TVT Procedure
			CV of Katrin EK Elbert, PhD
	ETH.MESH.15406935	ETH.MESH.15406936	Guidoin Lab Notebook Page/Image
	ETH.MESH.15958503	ETH.MESH.15958507	Guidoin Lab Notebook Page/Image
	ETH.MESH.00998286	ETH.MESH.00998291	Weisberg M Final Draft CER
	ETH.MESH.12907175	ETH.MESH.12907175	Spreadsheet Revision History - Defect to Harms Map
	ETH.MESH.04321409	ETH.MESH.04321412	Check Liste D-Inspection Qualite
	ETH.MESH.05210364	ETH.MESH.05210365	Mesh vs Non-Mesh Pending PR/Regulatory Issues

	ETH.MESH.03965159	ETH.MESH.03965195	Presentation: "The Science of "What's Left Behind"... Evidence & Follow-Up of Mesh Use for SUI by Doug H. Grier, MD"
8/23/2007	ETH.MESH.00000272	ETH.MESH.00000272	Macroporous email
2003	ETH.MESH.00015598	ETH.MESH.0015607	Cosson, et al. *Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material?* . Int Urogynecol J (2003) 14: 169-178
11/12/2008	ETH.MESH.00035379	ETH.MESH.00035380	Prolift +M Pre Reading
10/14/2008	ETH.MESH.00066960	ETH.MESH.00066960	10/14/08 Voice mail from Mahar
5/8/2005	ETH.MESH.00126755	ETH.MESH.00126757	Email re: DRAFT FDA Response on Prolift +M for input
9/22/2004	ETH.MESH.00126954	ETH.MESH.00126955	Email re: Preceptor "Voicemails"?
2004	ETH.MESH.00155598	ETH.MESH.00155600	2004 press release
From Metadata:01/01/05	ETH.MESH.00155619	ETH.MESH.0155627	Patient Brochure
	ETH.MESH.00158082	ETH.MESH.00158082	Tips for Scheduling you appoitnment
2000	ETH.MESH.00160615	ETH.MESH.00160623	TVT Brochure
1/16/2009	ETH.MESH.00161969	ETH.MESH.00161984	TVT Brochure
From Metadata: 01/06/06	ETH.MESH.00162841	ETH.MESH.00162856	TVT Brochure
2007	ETH.MESH.00163644	ETH.MESH.00163659	Patient Brochure
10/21/2008	ETH.MESH.00164023	ETH.MESH.00164027	FDA Notification About Use of Surgical Mesh
2/24/2011	ETH.MESH.00250986	ETH.MESH.00250986	TVT Training.xls
1/6/2006	ETH.MESH.00301874	ETH.MESH.00301875	Email re 50% mesh elongation
10/31/2005	ETH.MESH.00311832	ETH.MESH.00311832	IIS Process
2/1/2005	ETH.MESH.00316780	ETH.MESH.00316783	TVT Literature Search Review Summary
10/13/2008	ETH.MESH.00329112	ETH.MESH.00329113	10/13/08 Email from Paine
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10/17/2002	ETH.MESH.00766347	ETH.MESH.00766349	Ogilvy Public Relations Worldwide
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3/14/2008	ETH.MESH.01265223	ETH.MESH.01265239	Risk Management Report
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12/20/2006	ETH.MESH.01784428	ETH.MESH.01784435	Email re TVT-S Cookbooks
12/17/2004	ETH.MESH.01809082	ETH.MESH.01809083	Memo: VOC on new Laser Cut TVT Mesh
10/18/2006	ETH.MESH.01822361	ETH.MESH.01822363	10/18/06 Email from Dan Smith
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	ETH.MESH.PM 000027	ETH.MESH.PM 000027	Video
	ETH.MESH.PM 000032	ETH.MESH.PM 000032	Video
	ETH.MESH.PM 000037	ETH.MESH.PM 000037	Video
	ETH.MESH.PM 000039	ETH.MESH.PM 000039	Video
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Deponent	Date
Zenobia Wajli	All dates
Judy Gauld	All dates
Scott Ciarrocca	All dates
Matthew Henderson	All dates
Paul Parisi	All dates
Bryan Lisa	All dates
Sean O'Bryan	All dates
Angelini, Laura, Transcripts and Exhibits	All dates
Arnaud, Axel, MD Transcripts and Exhibits	All dates
Barbolt, Thomas A., Ph.D Transcripts and Exhibits	10/10/2012; 08/04/2013; 08/15/2013; 01/07/2014; 01/08/2014
Batke, Boris Transcripts and Exhibits	8/1-2/2013
Beath, Catherine Transcripts and Exhibits	07/11-12/2013
Burkley, Dan Transcripts and Exhibits	5/22/2013; 5/23/2013
Chen, Meng, MD Transcripts and Exhibits	10/29-30/2013
London-Brown, Allison Transcripts and Exhibits	All dates
Hart, James D., MD Transcripts and Exhibits	09/17/2013; 12/20/2013
Hellhammer, Brigette, MD Transcripts and Exhibits	09/11-12/2013
Hinoul, Piet Transcripts and Exhibits	04/05/2012; 06/26-27/2013; 01/13-15/2014
Holste, Joerg Transcripts and Exhibits	07/29-30-2013
Horton, Ron Transcripts and Exhibits	7/1/2015
Isenberg, Richard, MD Transcripts and Exhibits	11/5/13 and 11/6/13

Divilio, Thomas Transcrips and Exhibits	All dates
Kirkemo, Aaron, Transcripts and Exhibits	All dates
Kammerer, Gene, Transcript and Exhibits	All dates
Lin, Susan, Transcripts and Exhibits	3/12-13/2013; 05/3,6/2013; 08/01/2013
Lamont, Daniel J. Transcript	4/3-4/2013; 9/11/2013
Owens, Charlotte Transcript and Exhibits	9/12/2012; 6/20/2013
Robinson, David Transcripts and Exhibits	07/24-25/2013; 09/11/2013
Selman, Renee Transcript and Exhibits	6/21/2013
Smith, Dan, Transcripts and Exhibits	05/15-16/2013; 06/04-05/2013; 08/20-21/2013
Vailhe, Christophe, Ph.D., Transcripts and Exhibits	06/20-21/2013
Weisberg, Martin, MD Transcripts and Exhibits	05/30-31/2013; 08/09/2013
McCoy, Sheri Transcripts and Exhibits	All dates
Yale, Mark, Transcript and Exhibits	8/7/2013
Trial Testimony of Piet Hinoul - Batiste v. Ethicon	3/26/14; 3/27/14; 3/28/14
Jones, Scot Transcript and Exhibits	6/9/2014
Testimony and Exhibits from Batiste v. Ethicon Trial	

Deposition of Bruce Rosenzweig, MD	9/22/2015
Deposition of Jerry Blaivas, MD	9/17/2015

Expert Reports
Dr. Bruce Rosenzweig
Dr. Jerry Blaivas
Dr. John Miklos
Dr. Scott Guelcher
Dr. Jimmy Mays
Dr. Anne Wilson
Dr. Howard Jordi
Dr. Vlad Iakovlev
Dr. Uwe Klinge
Dr. Thomas Muehl
Dr. Suzanne Parisian
Duane Priddy, Ph.D.